CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Certificate of Need

(Amended After Comments)

900 KAR 5:020. State Health Plan for facilities and services.

RELATES TO: KRS 216B.010-216B.130

STATUTORY AUTHORITY: KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), 216B.040(2)(a)2.a.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)2.a requires the cabinet to promulgate an administrative regulation, updated annually, to establish the State Health Plan. The State Health Plan is a critical element of the certificate of need process for which the cabinet is given responsibility in KRS Chapter 216B. This administrative regulation establishes the State Health Plan for facilities and services.

Section 1. The 2018 Update to the 2017-2019 State Health Plan shall be used to:

(1) Review a certificate of need application pursuant to KRS 216B.040; and

(2) Determine whether a substantial change to a health service has occurred pursuant to KRS 216B.015(29)(a) and 216B.061(1)(d).

Section 2. Incorporation by Reference. (1) The "2018 Update to the 2017-2019 State Health Plan", October **15,** 2018[~~November 2017~~], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, Division of Certificate of Need[~~Health~~

~~Policy~~], 275 East Main Street, 5E-A[~~4WE~~], Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

900 KAR 5:020

10-11-18

Steve Davis, Inspector General — Date
Office of Inspector General

APPROVED:

10/11/18

Adam M. Meier, Secretary — Date
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 900 KAR 5:020
Contact Persons: Molly Lewis, 502-564-9592, molly.lewis@ky.gov; or Laura Begin, (502) 564-6746, CHFSRegs@ky.gov.

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation incorporates by reference the 2018 Update to the 2017-2019 State Health Plan, which shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), and 216B.040(2)(a)2.a.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by incorporating by reference the 2018 Update to the 2017-2019 State Health Plan, which shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. KRS 216B.015(28) requires that the State Health Plan be prepared triennially and updated annually.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: The State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment incorporates by reference the 2018 Update to the 2017-2019 State Health Plan. Changes in the Amended After Comments version include:

- The identifying information on the front page was changed to reflect the new version's date;
- The Table of Contents was changed to reflect new page numbers as a result of the other changes and to align titles;
- Revise Acute Care Bed Review Criteria to delete Review Criterion 4, which allowed existing licensed hospitals verified as trauma centers and operating beds pursuant to an emergency CON to apply for a CON to provide the emergency services on a permanent basis and be found consistent with the State Health Plan;
- Revise Special Care Neonatal Bed Definitions and Review Criteria to clarify that Advanced Level II is not a recognized provider type;
- Revise Special Care Neonatal Bed Review Criteria to allow hospitals with Level II neonatal beds operating at functional capacity for a year to apply to establish up to eight (8) Level II beds and be found consistent with the State Health Plan;
- Revise Special Care Neonatal Bed Review Criteria to clarify the intent to provide hospitals with existing acute care bed capacity the flexibility to convert acute care beds to meet the needs of complex neonatal beds. (This clarification distinguishes

this existing criterion ("through conversion") from the new criterion, which addressed establishing Level II special care neonatal beds);

- Revise Psychiatric Bed Review Criteria to limit review criterion addressing an existing psychiatric hospital's conversion of existing beds from beds of any licensure type to tuberculosis beds;
- Revise Psychiatric Services for Children and Adolescents Review Criteria to require the application for new psychiatric beds to include an inventory of all facilities with children or adolescent psychiatric beds in the ADD and the number of beds, rather than an inventory of current services in the ADD (which did not specify the type of services so was overly broad)
- Revise Psychiatric Residential Treatment Facility Review Criteria to delete the 145 bed cap for Level II PRTFs;
- Revise Psychiatric Residential Treatment Facility Review Criteria to delete criteria allowing psychiatric hospitals applying to use converted existing bed capacity to a Level II PRTF to be consistent with State Health Plan;
- Revise Long Term Care Review Criteria Definitions and Review Criteria to delete references and application to Specialized Long Term Care programs;
- Revise Long Term Care Review Criteria to delete review criteria allowing existing acute care hospitals qualified to establish post-acute nursing facilities limited exclusively to specific patient population and model of care notwithstanding the need calculation for the county;
- Revise Long Term Care Review Criteria to add review criteria specifically addressing existing facilities operating pursuant to emergency certificate of need authorization to apply for permanent authorization to provide services restricted to the limited purpose of alleviating the emergency specific to ventilator dependent patients that require long-term ventilator services and be consistent with the State Health Plan notwithstanding the need calculation for the county;
- Revise Home Health Agency Definition to reflect statutory definition in KRS 216.935(2);
- Revise Home Health Agency Long-Term Care Review Criteria to limit review criteria allowing existing hospitals and nursing facilities experiencing challenges with patient discharge to establish a home health agency limited to patients discharged from that facility and be consistent with the State Health Plan notwithstanding the need calculation for the county;
- Revise Cardiac Catheterization Services Review Criteria for establishing a comprehensive catheterization program by further defining qualifications for the applicant hospital and its relationship to a Kentucky academic medical center;
- Revise Cardiac Catheterization Services Review Criteria to allow mobile catheterization services to convert to fixed site catheterization services;
- Delete review criteria for Magnetic Resonance Imaging from the State Health Plan;
- Revise Positron Emission Tomography Equipment Review Criteria to add review criterion to allow the establishment and expansion of mobile services with arrangements and support of a hospital in the service area;
- Revise Ambulance Services Definition and Review Criteria to revise the definition section, cross-reference the applicable statutory and regulatory provisions, clarify geographic service area requirements for applicants, and delete the review

criterion addressing application components and review prioritization for Class II or Class III services;

- Revise the Acute Care Hospital Review Criterion 2.e. to change "or" to "and";
- Revise the Nursing Facility Beds Definition to remove a reference to Plan provisions for continuing care retirement communities; and
- Additional nonsubstantive changes were made throughout the State Health Plan to comply with the drafting and formatting requirements of KRS Chapter 13A. These nonsubstantive changes include the following types of changes:
    - Correcting a Web site address;
    - Changing "recent" to "recently" in the phrase "most recent published";
    - Changing "which" to "that";
    - Changing "its" to "the applicant's";
    - Correcting a cross-reference;
    - Changing "applications" to "an application" and other singular-plural changes;
    - Changing "outlined" to "established";
    - Dividing a compound sentence into two sentences for clarity;
    - Defining an acronym; and
    - Adjusting punctuation.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to update the State Health Plan, which is used to determine whether certificate of need applications are consistent with the State Health Plan. Additionally, the Amended After Comments changes were necessary to respond to comments received during the public comment period.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statutes by incorporating by reference the 2018 Update to the 2017-2019 State Health Plan.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will provide the 2018 Update to the 2017-2019 State Health Plan, which will be used to determine whether certificate of need applications are consistent with the State Health Plan.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects certificate of need applicants and affected parties requesting hearings. Annually, approximately 115 certificate of need applications are filed.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities that submit certificate of need applications will be subject to the criteria set forth in the 2018 Update to the 2017-2019 State Health Plan.

(b) In complying with this administrative regulation or amendment, how much will it

cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Entities that submit certificate of need applications will be subject to the revised criteria set forth in the 2018 Update to the 2017-2019 State Health Plan.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional costs will be incurred to implement this administrative regulation.

(b) On a continuing basis: No additional costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No new funding will be needed to implement the provision of the amended administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No fee or funding increase is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: The administrative regulation does not establish or increase fees.

(9) TIERING: Is tiering applied? Yes, tiering is used as there are different CON review criteria for each licensure category addressed in the State Health Plan.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 900 KAR 5:020
Contact Persons: Molly Lewis, 502-564-7905, molly.lewis@ky.gov; or Laura Begin, (502) 564-6746, CHFSregs@ky.gov.

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and may impact any government owned or controlled health care facilities.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030, 194A.050(1), 216B.010, 216B.015(28), and 216B.040(2)(a)2.a

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? No additional costs will be incurred to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? No additional costs will be incurred to implement this administrative regulation on a continuing basis.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):
Expenditures (+/-):
Other Explanation:

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Certificate of Need

900 KAR 5:020. State Health Plan for facilities and health services.

The 2018 Update to the 2017 – 2019 State Health Plan, October 15, 2018, is incorporated by reference. The 2018 Update to the 2017-2019 State Health Plan shall be used to determine whether applications for certificates of need are consistent with plans as required by KRS 216B.040(2)(a)2.a. Changes made to the State Health Plan as noted in the Amended After Comments administrative regulation include:

- The identifying information on the front page was changed to reflect the new version's date;
- The Table of Contents was changed to reflect new page numbers as a result of the other changes and to align titles;
- Revise Acute Care Bed Review Criteria to delete Review Criterion 4, which allowed existing licensed hospitals verified as trauma centers and operating beds pursuant to an emergency CON to apply for a CON to provide the emergency services on a permanent basis and be found consistent with the State Health Plan;
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- Revise Special Care Neonatal Bed Review Criteria to clarify the intent to provide hospitals with existing acute care bed capacity the flexibility to convert acute care beds to meet the needs of complex neonatal beds. (This clarification distinguishes this existing criterion ("through conversion") from the new criterion, which addressed establishing Level II special care neonatal beds);
- Revise Psychiatric Bed Review Criteria to limit review criterion addressing an existing psychiatric hospital's conversion of existing beds from beds of any licensure type to tuberculosis beds;
- Revise Psychiatric Services for Children and Adolescents Review Criteria to require the application for new psychiatric beds to include an inventory of all facilities with children or adolescent psychiatric beds in the ADD and the number of beds, rather than an inventory of current services in the ADD (which did not specify the type of services so was overly broad)
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Level II PRTF to be consistent with State Health Plan;

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- Revise Cardiac Catheterization Services Review Criteria for establishing a comprehensive catheterization program by further defining qualifications for the applicant hospital and its relationship to a Kentucky academic medical center;
- Revise Cardiac Catheterization Services Review Criteria to allow mobile catheterization services to convert to fixed site catheterization services;
- Delete review criteria for Magnetic Resonance Imaging from the State Health Plan;
- Revise Positron Emission Tomography Equipment Review Criteria to add review criterion to allow the establishment and expansion of mobile services with arrangements and support of a hospital in the service area;
- Revise Ambulance Services Definition and Review Criteria to revise the definition section, cross-reference the applicable statutory and regulatory provisions, clarify geographic service area requirements for applicants, and delete the review criterion addressing application components and review prioritization for Class II or Class III services;
- Revise the Acute Care Hospital Review Criterion 2.e. to change "or" to "and";
- Revise the Nursing Facility Beds Definition to remove a reference to Plan provisions for continuing care retirement communities; and
- Additional nonsubstantive changes were made throughout the State Health Plan to comply with the drafting and formatting requirements of KRS Chapter 13A.

Total number of pages - 57

The total number of pages incorporated by reference in this administrative regulation is 57.

STATEMENT OF CONSIDERATION RELATING TO
900 KAR 5:020

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Certificate of Need

Amended After Comments

I. A public hearing on 900 KAR 5:020 was held on August 27, 2018, at 9:00 a.m. in the Health Services Building, 275 East Main Street, Frankfort, Kentucky. Additionally, written comments were received during the public comment period.

II. The following people submitted comments during the public hearing and public comment period or attended the public hearing without commenting:

Name	Organization
Michael R. Ewing	Amedisys Home Health
Hollie Harris Phillips	Appalachian Regional Healthcare
Dr. Robert H. Long	Baptist Life Communities
Teresa Kiskaden	Bluegrass Health Partners
Cameron Cook	Brightmore Home Care of Kentucky, LLC
Christian McCutcheon	BrightStar Care of Louisville
Chris McCreary	BrightStar Care of Northern Kentucky
Michelle Sanborn	Children's Alliance
Barbara Kinder	Clark Regional Medical Center
Holly Turner Curry	Cull & Hayden, P.S.C.*
Maribeth Shelton	Cumberland Valley Manor
Mathew R. Klein	DBL Law, on behalf of SUN Behavioral Health Kentucky
Jason Gumm	Diversicare of Glasgow
Tom Davis	Diversicare of Nicholasville
Robert Flatt	Essex Nursing and Rehab
Truly Pennington	Grand Haven Nursing Home
Abby Flint	Greenwood Nursing and Rehab Center
Amanda Drone	Greenwood Nursing and Rehab Center
Amanda Keller	Greenwood Nursing and Rehab Center
Amanda Steffly	Greenwood Nursing and Rehab Center
Amy Dye-Spann	Greenwood Nursing and Rehab Center

April Smith	Greenwood Nursing and Rehab Center
Ashley Brown	Greenwood Nursing and Rehab Center
Bethann Daugherty	Greenwood Nursing and Rehab Center
Bonnie Fleischman	Greenwood Nursing and Rehab Center
Brandi Blanchard	Greenwood Nursing and Rehab Center
Chrissy Laz	Greenwood Nursing and Rehab Center
Connie Parker	Greenwood Nursing and Rehab Center
Connie Stamper	Greenwood Nursing and Rehab Center
Cory Wilkins	Greenwood Nursing and Rehab Center
Cynthia Sarazin	Greenwood Nursing and Rehab Center
Dana R. Bird	Greenwood Nursing and Rehab Center
Debi Davis	Greenwood Nursing and Rehab Center
Donita Brown	Greenwood Nursing and Rehab Center
Donna Haycraft	Greenwood Nursing and Rehab Center
Elisa James	Greenwood Nursing and Rehab Center
Ellen P. Staller	Greenwood Nursing and Rehab Center
Hailey Fritz	Greenwood Nursing and Rehab Center
Helen Corley	Greenwood Nursing and Rehab Center
Jane Huff	Greenwood Nursing and Rehab Center
Jonathan McGuire	Greenwood Nursing and Rehab Center
Julie Hunt	Greenwood Nursing and Rehab Center
Kate Bradley	Greenwood Nursing and Rehab Center
Kathleen Warren	Greenwood Nursing and Rehab Center
Kayla Burton	Greenwood Nursing and Rehab Center
Kimberly A. Stevens	Greenwood Nursing and Rehab Center
Kimberly Walker	Greenwood Nursing and Rehab Center
Linda McMurphy	Greenwood Nursing and Rehab Center
Lisa Smith	Greenwood Nursing and Rehab Center
Maureen Brackshaw	Greenwood Nursing and Rehab Center
Melissa Bouldin	Greenwood Nursing and Rehab Center
Melody Lawson	Greenwood Nursing and Rehab Center
Mendi Willis	Greenwood Nursing and Rehab Center
Michelle Cline	Greenwood Nursing and Rehab Center
Nancy Parsley	Greenwood Nursing and Rehab Center
Pine Ruby	Greenwood Nursing and Rehab Center
Rebecca Lyne	Greenwood Nursing and Rehab Center
Richard Brannon	Greenwood Nursing and Rehab Center
Robert McClintock	Greenwood Nursing and Rehab Center
Ronda Wright	Greenwood Nursing and Rehab Center
Roxanne Nordike	Greenwood Nursing and Rehab Center
Seth Denton	Greenwood Nursing and Rehab Center

Sheena Dickson	Greenwood Nursing and Rehab Center
Shelia Minnicks	Greenwood Nursing and Rehab Center
Sherri Jones	Greenwood Nursing and Rehab Center
Susie Korfits Broch	Greenwood Nursing and Rehab Center
Tammy Forgy	Greenwood Nursing and Rehab Center
Teresa Steinbergen	Greenwood Nursing and Rehab Center
Teri Elrod	Greenwood Nursing and Rehab Center
Toya Boards	Greenwood Nursing and Rehab Center
Vickie Ramjon	Greenwood Nursing and Rehab Center
28 Other Representatives with Signatures that were Not Legible	Greenwood Nursing and Rehab Center
Melodie Bingham	Hargis and Associates, LLC
Rhonda Houchens	Hargis and Associates, LLC
Darlene Litteral	Health Directors, inc, and Professional Home Health Care Agency, Inc.
Jay H. Trumbo	Health Systems of Kentucky
Kim Gibbons	Hicks Golden Years Nursing Home
Colleen McKinley	Interim Healthcare of Northern Kentucky
Doris Ecton	Johnson Mathers Nursing Home
Elizabeth A. "Betsy" Johnson	Kentucky Association of Health Care Facilities/Kentucky Center for Assisted Living
Bruce T. Linder	Kentucky Association of Health Care Facilities/Kentucky Center for Assisted Living*
Mark Bowman	Kentucky Association of Health Care Facilities/Kentucky Center for Assisted Living*
Wayne Johnson	Kentucky Association of Health Care Facilities/Kentucky Center for Assisted Living*
Charles R. "Chuck" O'Neal	Kentucky Board of Emergency Medical Services
Michael T. Rust	Kentucky Hospital Association
Jessica Hall	Knott County Health and Rehab Center
Ruby Pigman	Knott County Health and Rehab Center
Angela Reaves	Lake Way Nursing and Rehab
Ashley Dixon	Lake Way Nursing and Rehab
Buddy Price	Lake Way Nursing and Rehab
Carlia Tazmen	Lake Way Nursing and Rehab
Ellen Warren	Lake Way Nursing and Rehab
Heather Gamble	Lake Way Nursing and Rehab
Kathy Morehead	Lake Way Nursing and Rehab
Lisa Duncan	Lake Way Nursing and Rehab
Madonna Edwards	Lake Way Nursing and Rehab
Melissa Mitzy	Lake Way Nursing and Rehab
Melissa Price	Lake Way Nursing and Rehab

Molly LaVerdi	Lake Way Nursing and Rehab
Suzanne Lewis	Lake Way Nursing and Rehab
Sylvia Jestes	Lake Way Nursing and Rehab
Tammy Crittenden	Lake Way Nursing and Rehab
Tammy York	Lake Way Nursing and Rehab
Tatum York	Lake Way Nursing and Rehab
Teresa Brasher	Lake Way Nursing and Rehab
Tia Collins	Lake Way Nursing and Rehab
Tiffany Hayden	Lake Way Nursing and Rehab
Tevis Tuggle	Landmark of Lancaster Rehabilitation and Nursing Center
Regina Lyons	Landmark of River City
Timothy L. Veno	LeadingAge Kentucky
Jay M. Frances	Legacy Health Services, Inc.
Susan Arnold	Management Advisors Inc.
John Dailey	Management Advisors Inc.
Emily Jones-Gray	Mountain Manor of Paintsville
Amy Elliott	Mountain View Nursing and Rehab Center
Ann Sexton	Mountain View Nursing and Rehab Center
April Sexton	Mountain View Nursing and Rehab Center
Baleli Tuttle	Mountain View Nursing and Rehab Center
Betty Miracle	Mountain View Nursing and Rehab Center
Brenda Watts	Mountain View Nursing and Rehab Center
Brittany McGreger	Mountain View Nursing and Rehab Center
Brodie Erwin	Mountain View Nursing and Rehab Center
Christal Nina	Mountain View Nursing and Rehab Center
Christina Marsle	Mountain View Nursing and Rehab Center
Christy Saylor	Mountain View Nursing and Rehab Center
Courtney Cinnamon	Mountain View Nursing and Rehab Center
Dannie Brock	Mountain View Nursing and Rehab Center
Hattie Rice	Mountain View Nursing and Rehab Center
Heather Ann Partin	Mountain View Nursing and Rehab Center
Heather Pocti	Mountain View Nursing and Rehab Center
Jamie Collett	Mountain View Nursing and Rehab Center
Jeannie M. Cox	Mountain View Nursing and Rehab Center
Jessica Miracle	Mountain View Nursing and Rehab Center
Karen Tigre	Mountain View Nursing and Rehab Center
Kathy Hoskins	Mountain View Nursing and Rehab Center
Kathy Miller	Mountain View Nursing and Rehab Center
Kimberly Gambrel	Mountain View Nursing and Rehab Center
Lauren Ausmus	Mountain View Nursing and Rehab Center

Lena Brock	Mountain View Nursing and Rehab Center
Lena Goodin	Mountain View Nursing and Rehab Center
Linda Webb	Mountain View Nursing and Rehab Center
Marie Tresure	Mountain View Nursing and Rehab Center
Mary J. Balkins	Mountain View Nursing and Rehab Center
Matthew Farme	Mountain View Nursing and Rehab Center
Melanie Lewis	Mountain View Nursing and Rehab Center
Merle Middleton	Mountain View Nursing and Rehab Center
Mitzy Oneski	Mountain View Nursing and Rehab Center
Pansy Scott	Mountain View Nursing and Rehab Center
Robert Britton	Mountain View Nursing and Rehab Center
Rodney Elliott	Mountain View Nursing and Rehab Center
Rose Aldridge	Mountain View Nursing and Rehab Center
Russell Lambert	Mountain View Nursing and Rehab Center
Sandy Baker	Mountain View Nursing and Rehab Center
Savannah West	Mountain View Nursing and Rehab Center
Shelly Johnson	Mountain View Nursing and Rehab Center
Sherry Epperson	Mountain View Nursing and Rehab Center
Sherry Gray	Mountain View Nursing and Rehab Center
Sindy Brock	Mountain View Nursing and Rehab Center
Taylor Woodward	Mountain View Nursing and Rehab Center
Teresa Miracle	Mountain View Nursing and Rehab Center
Terri McDowell	Mountain View Nursing and Rehab Center
Tracy Hensley	Mountain View Nursing and Rehab Center
Vivian Lambert	Mountain View Nursing and Rehab Center
Yolanda Salas	Mountain View Nursing and Rehab Center
2 Other Representatives with Signatures that were Not Legible	Mountain View Nursing and Rehab Center
Lanna Roberts	Parkview Nursing and Rehab Center
Mark Millet	Pine Meadows Post Acute*
Brian W. Lebanion	Professional Home Health Care Agency, Inc.
Heidi Schissler Lanham	Protection and Advocacy
Stock Longhurst	Providence CP Louisville*
M. Wasim Sajid, M.D.	Purchase Youth Village
Rick Hendrickson	Redbanks Colonial Terrace Nursing Home
Allin Maupin	Rivers Edge Nursing and Rehab
Annette Sidney	Rivers Edge Nursing and Rehab
Bobby Jones	Rivers Edge Nursing and Rehab
Brian M. Murphy	Rivers Edge Nursing and Rehab
Brittany Kellogg	Rivers Edge Nursing and Rehab
Carrie Moore	Rivers Edge Nursing and Rehab

Chelsea Hail	Rivers Edge Nursing and Rehab
Colleen Smith	Rivers Edge Nursing and Rehab
Deborah J. Posey	Rivers Edge Nursing and Rehab
Diane Rabourn	Rivers Edge Nursing and Rehab
Donald Kern	Rivers Edge Nursing and Rehab
Donna Hoffs	Rivers Edge Nursing and Rehab
Earnestine Winbush	Rivers Edge Nursing and Rehab
Edward Bennett	Rivers Edge Nursing and Rehab
Erin Farley	Rivers Edge Nursing and Rehab
Faith Robinson	Rivers Edge Nursing and Rehab
Frank Anthony	Rivers Edge Nursing and Rehab
Heather Lilly	Rivers Edge Nursing and Rehab
Jackie Carlin	Rivers Edge Nursing and Rehab
Janice Sanford	Rivers Edge Nursing and Rehab
Jerushia Goodlett	Rivers Edge Nursing and Rehab
Joshua P. Wesley	Rivers Edge Nursing and Rehab
Karen Gilbert	Rivers Edge Nursing and Rehab
Kathryn Allen	Rivers Edge Nursing and Rehab
Kelly Curtis	Rivers Edge Nursing and Rehab
Lisa Hughes	Rivers Edge Nursing and Rehab
Lozetta Marie Rison	Rivers Edge Nursing and Rehab
Marilyn Malone	Rivers Edge Nursing and Rehab
Mary Beich	Rivers Edge Nursing and Rehab
Matthew McMichael	Rivers Edge Nursing and Rehab
Megan D. Wallmans	Rivers Edge Nursing and Rehab
Michael Klomp	Rivers Edge Nursing and Rehab
Michele Baugh	Rivers Edge Nursing and Rehab
Pam Peerce	Rivers Edge Nursing and Rehab
Ralph Matthis	Rivers Edge Nursing and Rehab
Rudy Shelley	Rivers Edge Nursing and Rehab
Samantha Kirman	Rivers Edge Nursing and Rehab
Sharese Sanders	Rivers Edge Nursing and Rehab
Sharon Polloch	Rivers Edge Nursing and Rehab
Sherry Brown	Rivers Edge Nursing and Rehab
Tabitha Andrews	Rivers Edge Nursing and Rehab
Tracy Gatt	Rivers Edge Nursing and Rehab
Victoria Wenzel	Rivers Edge Nursing and Rehab
16 Other Representatives with Signatures that were Not Legible	Rivers Edge Nursing and Rehab
Stephen A. Estes	Rockcastle Regional Hospital and Respiratory Care Center
Karen Stevens	Shared Medical Services, Inc.

Shelley Laneve	Shemwell HealthCare
Alisa Judd	Somerwoods Nursing and Rehab
Amanda Gretz	Somerwoods Nursing and Rehab
Amber Hoskins	Somerwoods Nursing and Rehab
Angel Meece	Somerwoods Nursing and Rehab
Angel Ward	Somerwoods Nursing and Rehab
Angela Anshear	Somerwoods Nursing and Rehab
Ashley Harris	Somerwoods Nursing and Rehab
Beth M. Quinn	Somerwoods Nursing and Rehab
Bethany Overly	Somerwoods Nursing and Rehab
Billie Bune	Somerwoods Nursing and Rehab
Brandon Row	Somerwoods Nursing and Rehab
Brenda Worley	Somerwoods Nursing and Rehab
Brian K. Jaggers	Somerwoods Nursing and Rehab
Brittany Collier	Somerwoods Nursing and Rehab
Brittany Williamson	Somerwoods Nursing and Rehab
Caitlyn Amkrite	Somerwoods Nursing and Rehab
Calli Thomas	Somerwoods Nursing and Rehab
Carolyn L. Bruhn	Somerwoods Nursing and Rehab
Chelsea King	Somerwoods Nursing and Rehab
Clara Begley	Somerwoods Nursing and Rehab
Craig C. Wesly	Somerwoods Nursing and Rehab
Crystal Thurman	Somerwoods Nursing and Rehab
Dan Helm	Somerwoods Nursing and Rehab
Daniel Parker	Somerwoods Nursing and Rehab
Danielle Pence	Somerwoods Nursing and Rehab
Deborah Godby	Somerwoods Nursing and Rehab
Diane Rose	Somerwoods Nursing and Rehab
Dina C. Lay	Somerwoods Nursing and Rehab
Donna Gray	Somerwoods Nursing and Rehab
Dora Buster	Somerwoods Nursing and Rehab
Elisi Phelps	Somerwoods Nursing and Rehab
Emanual Leacy	Somerwoods Nursing and Rehab
Frances A. Evans	Somerwoods Nursing and Rehab
Francis Hines	Somerwoods Nursing and Rehab
Heather Hammer	Somerwoods Nursing and Rehab
Jacob L. Scott	Somerwoods Nursing and Rehab
Jamie Saunders	Somerwoods Nursing and Rehab
Jay Hall	Somerwoods Nursing and Rehab
Jean Kemper	Somerwoods Nursing and Rehab
Jennifer Baker	Somerwoods Nursing and Rehab

Jennifer Gregory	Somerwoods Nursing and Rehab
Jessica Slone	Somerwoods Nursing and Rehab
Jessica Stacey	Somerwoods Nursing and Rehab
Kaitlyn Shut	Somerwoods Nursing and Rehab
Karen Bunch	Somerwoods Nursing and Rehab
Kathy Cook	Somerwoods Nursing and Rehab
Kathy Tucker	Somerwoods Nursing and Rehab
Kayla Adams	Somerwoods Nursing and Rehab
Kelai Ragan Miller	Somerwoods Nursing and Rehab
Kimberly Decker	Somerwoods Nursing and Rehab
Leslie Barrett	Somerwoods Nursing and Rehab
Lindsey Bowling	Somerwoods Nursing and Rehab
Lisa Boyd	Somerwoods Nursing and Rehab
Lisa G. Brown	Somerwoods Nursing and Rehab
Mary G. Whitens	Somerwoods Nursing and Rehab
Melissa Strink	Somerwoods Nursing and Rehab
Meredith Surber	Somerwoods Nursing and Rehab
Mesha McIntosh	Somerwoods Nursing and Rehab
Misty Campbell	Somerwoods Nursing and Rehab
Nakkita Ard	Somerwoods Nursing and Rehab
Pat Knapp	Somerwoods Nursing and Rehab
Patricia B. Dean	Somerwoods Nursing and Rehab
Patty Murphy	Somerwoods Nursing and Rehab
Peggy Holden	Somerwoods Nursing and Rehab
Phyllis Hunt	Somerwoods Nursing and Rehab
Robbie Ramsey	Somerwoods Nursing and Rehab
Rosa Pruitt	Somerwoods Nursing and Rehab
Rosemary Cross	Somerwoods Nursing and Rehab
Samy Cald	Somerwoods Nursing and Rehab
Sarah Lay	Somerwoods Nursing and Rehab
Stacey J. Bates	Somerwoods Nursing and Rehab
Stephanie Dick	Somerwoods Nursing and Rehab
Surey M. Brooks	Somerwoods Nursing and Rehab
Sylvia McCormick	Somerwoods Nursing and Rehab
Tamara Kingsley	Somerwoods Nursing and Rehab
Teresa Matthews	Somerwoods Nursing and Rehab
Tiffany Cook	Somerwoods Nursing and Rehab
Tiffany Huff	Somerwoods Nursing and Rehab
Tiffany McKillen	Somerwoods Nursing and Rehab
Tonia Miller	Somerwoods Nursing and Rehab
Tonya Reynolds	Somerwoods Nursing and Rehab

Tyler Baker	Somerwoods Nursing and Rehab
Violet Rose	Somerwoods Nursing and Rehab
Virginia Ramsay	Somerwoods Nursing and Rehab
Wanda Rose	Somerwoods Nursing and Rehab
15 Other Representatives with Signatures that were Not Legible	Somerwoods Nursing and Rehab
Dr. Ralph Alvarado	State Senator
Janet A. Craig	Stites and Harbison, PLLC on behalf of Pikeville Medical Center
Steve Johnson	SVBC*
Angel Harrell	Tri-Cities Nursing and Rehabilitation Center
Ann Epperson	Tri-Cities Nursing and Rehabilitation Center
April Kidwell	Tri-Cities Nursing and Rehabilitation Center
Ashly Page	Tri-Cities Nursing and Rehabilitation Center
Brittany Baily	Tri-Cities Nursing and Rehabilitation Center
Christy Roark	Tri-Cities Nursing and Rehabilitation Center
Della Baker	Tri-Cities Nursing and Rehabilitation Center
Donna Repperson	Tri-Cities Nursing and Rehabilitation Center
Dorothy Smith	Tri-Cities Nursing and Rehabilitation Center
Ginger Fletcher	Tri-Cities Nursing and Rehabilitation Center
Ginger Turner	Tri-Cities Nursing and Rehabilitation Center
Heather Ewing	Tri-Cities Nursing and Rehabilitation Center
Heather R. Huff	Tri-Cities Nursing and Rehabilitation Center
Janel V. Adams	Tri-Cities Nursing and Rehabilitation Center
Jeff Wilder	Tri-Cities Nursing and Rehabilitation Center
Jessica N Lewis	Tri-Cities Nursing and Rehabilitation Center
Kayla Lewis	Tri-Cities Nursing and Rehabilitation Center
Kendra Nortl	Tri-Cities Nursing and Rehabilitation Center
Kristi Whitehead	Tri-Cities Nursing and Rehabilitation Center
Lamborghini Greene	Tri-Cities Nursing and Rehabilitation Center
Lori Hodge	Tri-Cities Nursing and Rehabilitation Center
Marsha Powers	Tri-Cities Nursing and Rehabilitation Center
Mary Beth Craig	Tri-Cities Nursing and Rehabilitation Center
Mary Combs	Tri-Cities Nursing and Rehabilitation Center
Mitzi Huff	Tri-Cities Nursing and Rehabilitation Center
Pam Raleigh	Tri-Cities Nursing and Rehabilitation Center
Rachel Lunford	Tri-Cities Nursing and Rehabilitation Center
Sarah Hinkle	Tri-Cities Nursing and Rehabilitation Center
Sharon Ison	Tri-Cities Nursing and Rehabilitation Center
Terenia Bledsoe	Tri-Cities Nursing and Rehabilitation Center
Teresa Turner	Tri-Cities Nursing and Rehabilitation Center
Tiffany Harris	Tri-Cities Nursing and Rehabilitation Center

Tonya Turner	Tri-Cities Nursing and Rehabilitation Center
Trena Ison	Tri-Cities Nursing and Rehabilitation Center
Vickie Fortets	Tri-Cities Nursing and Rehabilitation Center
4 Other Representatives with Signatures that were Not Legible	Tri-Cities Nursing and Rehabilitation Center
Terry L. Skaggs	Wells Health Systems and Kentucky Association of Health Care Facilities (KAHCF)
Michael D. Baker	Wyatt Tarrant & Combs LLP*

*These individuals attended the public hearing but did not comment on the administrative regulation.

III. The following people from the promulgating administrative body responded to the comments received:

Name and Title	Department
Molly Lewis, Deputy Inspector General	Cabinet for Health and Family Services, Office of Inspector General
Donna Little, Deputy Executive Director	Cabinet for Health and Family Services, Office of Legislative and Regulatory Affairs

IV. SUMMARY OF COMMENTS AND RESPONSES

(1) Subject: Acute Care Beds – Proposal to Add New Criterion Regarding Level I and II Trauma Centers

(a) Comment: Two comments were received regarding a proposed amendment to the review criteria for acute care beds for Level I and II trauma centers. An attorney representing Pikeville Medical Center, Inc. testified at public hearing and submitted a comment in support of this additional criterion, while the Kentucky Hospital Association submitted a comment in opposition to that additional criterion. Both comments are included and summarized as part of this comment. (The comments relate to "I. Acute Care; B. Acute Care Beds; Review Criteria".)

1. Comment: Janet A. Craig, Attorney, Stites & Harbison, PLLC, stated that she was commenting on behalf of Pikeville Medical Center, Inc. (PMC). PMC is a not-for-profit hospital located in Pike County that has provided care for over 92 years. The comments state: "PMC is a regional referral center and a verified Level II Trauma Center. PMC offers more than 400 services, has essentially every medical specialty, and has an extensive list of subspecialties. PMC has more than one physician practicing in and 24/7 coverage of most specialties. PMC currently has 260 licensed acute care beds, 40 licensed inpatient rehabilitation beds, and recently received approval for a certificate of need to add an additional 60 acute care beds (40 new acute care beds and conversion of 20 of its rehabilitation beds)." PMC had previously submitted a comment requesting

the addition of a fourth criterion for acute care beds. The requested criterion, which was included in the proposed State Health Plan, amends "I. Acute Care; B. Acute Care Beds; Review Criteria", and reads as follows:

> 4. Notwithstanding criteria 1, 2, and 3, an application by an existing licensed acute care hospital shall be consistent with this Plan if the licensed acute care hospital:
> a. Is verified as a Level I or Level II Trauma Center; and
> b. Has received written acknowledgement from the Cabinet for Health and Family Services, Office of Inspector General, Division of Certificate of Need, recognizing that an emergency exists with respect to acute care beds being applied for.

2. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in opposition to the inclusion of Criterion 4, which was proposed by Pikeville Medical Center prior to the comment period and incorporated in the proposed State Health Plan. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible. Mr. Rust stated that member hospitals opposed the proposed revision adding Criterion 4 to the acute care bed criteria because they believe the criteria is not necessary and the current State Health Plan provides enough flexibility to allow hospitals with high occupancy to add acute care beds.

(b) Response: The Cabinet appreciates the comments regarding the proposal to add new criterion to the Review Criteria for Acute Care Beds regarding Level I and II trauma centers. The Cabinet will amend the State Health Plan to delete Criterion 4 from the Review Criteria for Acute Care Beds proposed in the 2018 Update to the 2017-2019 State Health Plan. Trauma center verification is done by The American College of Surgeons and the process includes verifying that a trauma center has the necessary resources for delivering optimal trauma care. University of Kentucky Hospital and University of Louisville Hospital are Kentucky's two Level I trauma centers and Pikeville Medical Center is the Commonwealth's only Level II trauma center. These three hospitals are Kentucky's university-based teaching hospitals and are responsible for treating Kentucky's most acute patients. The existing review criteria can be satisfied by any hospital at functional capacity (80% occupancy). Further, 900 KAR 6:080 allows for facilities, in emergency circumstances, to temporarily add beds to satisfy the emergency need. Because the existing criteria already addresses the issues outlined by Pikeville Medical Center, Criterion 4 is not necessary. In fact, Pikeville Medical Center recently obtained certificate of need authority (C/N # 098-11-394(33)) to add 40 acute care beds previously operated pursuant to an emergency acknowledged by the Cabinet per 900 KAR 6:080 when its application was deemed consistent with the current criteria. Without a cap or additional criteria linking the emergency to the inability to treat trauma patients, proposed Criterion 4 will be deleted to protect the overall objective of the certificate of need program to prevent the unnecessary proliferation of health services and facilities.

(2) Subject: Special Care Neonatal Beds, General

(a) Comment: One comment was received regarding revisions to the special care neonatal bed review criteria to remove specific language within the criteria with references to accepted national guidelines for neonatal care from the American College of Obstetrics and Gynecologists *Guidelines for Perinatal Care*. The references maintain the Plan's deference to the standard in the *Guidelines.*

Michael T. Rust, President, Kentucky Hospital Association, submitted comments in support of the revisions to the special care neonatal bed provisions. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible. He stated: "These changes include the removal of the specific redundant language within the criteria with references to accepted national guidelines for Neonatal Care. KHA supports these changes."

(b) Response: The Cabinet appreciates the comments regarding revisions to update the State Health Plan and will not be revising the State Health Plan in response to this comment of support.

(3) Subject: Special Care Neonatal Beds, Addition of Level II Beds

(a) Comment: One comment was received proposing an amendment to the review criteria for the Level II special care neonatal beds to allow the addition of beds when the facility documents high occupancy of its licensed beds. An attorney representing Pikeville Medical Center, Inc. (PMC) submitted a comment in support of this additional criterion.

Janet A. Craig, Attorney, Stites & Harbison, PLLC, stated that she was commenting on behalf of PMC. She also testified at public hearing and read her comments into the record. (This comment relates to "I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds".)

In her comment, Ms. Craig stated: "PMC currently has 260 licensed acute care beds, 40 licensed inpatient rehabilitation beds, and recently received approval for a certificate of need to add an additional 60 acute care beds (40 new acute care beds and conversion of 20 of its rehabilitation beds). It has 8 Level II NICU beds. PMC's acute bed occupancy as of the *2017 Hospital Services and Utilization Report* was 92.9 percent and its Level II NICU bed occupancy was 87.5%.

"On June 8, 2018, pursuant to the Division of CON's request for comments on the State Health Plan, PMC sent a letter to the Division suggesting a change to the ... Level II NICU criteria." The change suggested by PMC was not incorporated into the proposed administrative regulation as requested by PMC. PMC's comments repeat its request that the criterion for Level II special care neonatal beds be revised to state:

> Notwithstanding criteria 1 and 3, if the most recently published inventory and utilization data indicates that the applicant had 700 or more annual births and that the occupancy of the applicant's existing Level II special care neonatal beds or Advanced Level II special care neonatal beds was eighty (80) percent or greater, an application to add up to eight (8) additional Level II or Advanced Level II special care neonatal beds shall be consistent with

this Plan.

"The addition of this criterion would allow a hospital to add a limited number of Level II special care neonatal beds if a hospital is experiencing a high number of births and has a high occupancy in its existing Level II special care neonatal beds but does not have excess acute care beds available to convert to special care neonatal beds and other facilities in the region are not meeting the need. Under the current criteria, there is an avenue for hospitals to add Level II special care neonatal beds, despite criteria 1 and 3, by converting existing acute care beds. However, this avenue is not available to hospitals that have a high acute care bed occupancy and, as a result, do not have acute care beds to convert."

The comments added: "Without this change, seriously ill newborns may have to be transferred out of the service area, away from their families, to receive care when that care could be provided close to home."

(b) Response: The Cabinet appreciates the comments regarding the neonatal beds review criteria. The Cabinet recognizes the need for access to care and agrees that, if the hospitals are capable of delivering specified services, the Certificate of Need program should not be a barrier. At the request of PMC, the Cabinet has agreed to amend the State Health Plan; I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds to add the new criterion 9. Under the revised version of the State Health Plan, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds, Criterion 9 will provide as follows:

> Notwithstanding criteria 1 and 3, if the most recently published inventory and utilization data indicates that the applicant had 700 or more annual births and that the average occupancy of the applicant's existing Level II special care neonatal beds over twelve (12) months was eighty (80) percent or greater, an application to establish up to eight (8) additional Level II special care neonatal beds shall be consistent with this Plan;

It is the Cabinet's intent to allow a hospital to have needed, qualified flexibility to respond to its neonatal patient needs. Further, the transportation of these babies costs $4,000.00 to $6,000.00 per transport. According to the Public Health Neonatal Abstinence Syndrome (NAS) Reporting Registry, Kentucky has one of the highest incidence rates for NAS in the United States. Approximately 80% of the NAS births in Kentucky are to mothers with other children and most are covered by Medicaid. Transportation of these babies creates further complications for families already in stressful situations. Mothers and families have difficulty traveling to the baby as well as finding places to stay, among other issues. The revision will provide flexibility to hospitals treating complex neonatal patients, especially with the drastic increase of the diagnosis of NAS patients, when hospitals demonstrate a year of high occupancy. In responding to the opioid epidemic, the Cabinet recognizes the benefits of improving access to special care neonatal beds and reducing unnecessary transfers that could disrupt the mother-baby dyad when hospitals are qualified to deliver the services in a manner that is safe, effective and fosters the mother's recovery.

Additionally, to further clarify the difference between Criteria 9 and 10, Criterion 10 will be amended to add "through conversion" after a "Level II program". Criterion 10 will read as follows:

> Notwithstanding criteria 1 and 3, if the most recently published inventory and utilization data indicates that the applicant had 700 or more annual births, an application to establish a Level II program through conversion by designating up to eight (8) acute care beds as Level II special care neonatal beds shall be consistent with this Plan; and

(4) Subject: Special Care Neonatal Beds, Provision of Life Saving Care by Level II facility while waiting to transfer patient to higher level of care

(a) Comment: One comment was received proposing an amendment to the review criteria addressing the transferring of special care neonatal patients from Level II to a higher level of care. (This comment relates to "I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds".)

Janet A. Craig, Attorney, Stites & Harbison, PLLC, stated that she was commenting on behalf of Pikeville Medical Center (PMC). She also testified at the public hearing and read her comment into the record.

PMC currently operates 8 Level II NICU beds. In the comments, Ms. Craig states: "The current State Health Plan indicates that a Level II NICU should transfer patients 'requiring a higher level of respiratory support to a higher level of care.'... Given the distance between and to higher level NICUs in the state, there are instances when the administration of higher therapies (for example nitric oxide or cooling blankets) on a neonate immediately prior to and while awaiting transfer, could save the neonate's life. Specifically, when air travel is not possible, travel time to a higher level NICU takes longer. If the neonate cannot receive nitric oxide or other appropriate therapy while awaiting transfer to the higher level facility, there are situations when the neonate will not survive. Some of these therapies, for example, cooling blankets and certain heart medications, have therapeutics window of time in which they need to be utilized. Level IV facilities actually encourage transferring hospitals to utilize cooling protocols because, if it isn't done in the first six hours, it isn't effective. Basically, the SHP as proposed fails to take into account how long it can take a Level II located a long distance from a higher level facility to accomplish a transfer, especially during bad weather or unavailability of transport teams. PMC thinks Level II facilities should be able to do anything that the hospital has the equipment and staff qualified to perform as a life-saving measure while the hospital is trying to get the neonate to a higher level of care.

"While this change will not allow hospitals with Level II NICU to use these therapies for neonates who are remaining at the hospital for care, these hospitals need to be able to administer these therapies while awaiting transfers in these certain life threatening situations. As a result, we request the following language be added to Level II NICU Criterion 7.a.v.(c):

> In life threatening situations, a Level II or Advanced Level II NICU may provide any form of therapy that it has the equipment and qualified staff to perform while arranging and waiting for transfer of the neonate to a higher facility.

The addition of this language will save lives and is consistent with the other proposed changes in the SHP Level II criteria which were made to save lives of babies given the geography and availability of services in rural areas of Kentucky."

(b) Response: The Cabinet appreciates the comment addressing life threatening situations while a neonatal patient is awaiting transfer to a higher level of care. The Cabinet acknowledges the need to improve access to quality care but patient safety is paramount. Further, the requested language in the State Health Plan is not consistent with the 8th Edition of the Perinatal Guidelines, the national best practices adopted by the State Health Plan for neonatal care. Further the competencies, staffing, and support needs, for both medical personnel and hospitals, are significantly different for Level II, Level III, and Level IV special care neonatal services. The Cabinet recognizes that time is of the essence when treating a medically fragile infant but is confident that hospitals have the transfer and back-up plans in place to avoid delay and obtain access to the level of care needed. The interventions referenced in the criteria, including nitric oxide, cooling blankets, certain cardiac medications, or other therapeutic interventions require training, knowledge, and on-going efforts to acquire and maintain clinical competencies as well as resources such as respiratory therapy, blood bank, and diagnostic imaging that cannot be assured in a facility not licensed to provide the level of care. As such, the suggested revision is not included in the final version of the State Health Plan.

(5) Special Care Neonatal Beds: Clarification that Advanced Level II is not provider type

(a) Comment: One comment was received requesting additional revisions to provide clarification that Advanced Level II is not a special neonatal care provider type.

Michael T. Rust, President, Kentucky Hospital Association, submitted comments in support of the revisions to the special care neonatal bed provisions, but recommending language modification. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible. He stated: "...we have concerns that the term 'Advanced Level II' may be perceived as a new provider type in regards to licensure and could create licensure and operational problems for existing providers of this service." He suggested rewording to clarify that Level II providers may provide advanced care and that there is not a new provider type for "Advanced Level II" special neonatal care.

(b) Response: The Cabinet appreciates the comment requesting additional revisions to provide clarification that Advanced Level II is not a special neonatal care provider type. The Cabinet has implemented revisions to provide the requested clarification.

(6) Subject: Psychiatric Beds

(a) Comment: Two comments were received addressing the revision proposed by SUN Behavioral Health Kentucky to allow licensed psychiatric hospitals to convert beds licensed in another licensure category to psychiatric beds. The revision proposed by SUN Behavioral Health Kentucky was included in the proposed State Health Plan filed in July 2018. The Kentucky Hospital Association requested the proposed revision be limited to only allow conversion of beds licensed as tuberculosis beds and SUN Behavioral Health

Kentucky requested the same limitation. (This comment relates to "II. Behavioral Health Care; A. Psychiatric Beds".)

1. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in opposition to the proposed new Criterion 10 to permit a licensed psychiatric hospital to convert beds of any licensure classification to psychiatric beds if the facility's total number of licensed beds is not exceeded. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible. He stated: "KHA's member hospitals do not support this language as it is overly broad and could result in maldistribution of psychiatric services...

"KHA's members are concerned that the proposed language could have an unintended consequence of permitting facilities to convert beds in such a way as to allow the establishment of child/adolescent beds without meeting the Plan's specific requirements for those beds or to reduce access for specific patient populations if beds for a specific age group are converted. It is our understanding that this proposal may have been intended to address a specific problem of a psychiatric hospital needing the ability to convert licensed tuberculosis beds to psychiatric use. While KHA's members do not support the language found in the new criterion 10, our members do support a much more narrow exception to address this specific concern."

He suggested alternative language for criterion 10 limiting its applicability to permit only the conversion of licensed tuberculosis beds to psychiatric beds.

2. Comment: On behalf of SUN Behavioral Health Kentucky, Mathew R. Klein, Attorney, DBL Law, submitted comments addressing the State Health Plan review criteria for psychiatric beds: "SUN is a 197-bed psychiatric hospital in Erlanger, KY. The hospital was developed in partnership with Saint Elizabeth Healthcare, which transferred 140 psychiatric beds to SUN, and NorthKey Community Care, which transferred 57 beds to SUN. Of the 57 beds NorthKey transferred to SUN, 51 were psychiatric beds and 6 were tuberculosis beds. SUN appreciates that the draft State Health Plan addressed its concerns regarding psychiatric beds in review criterion number 10, which states:

> Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application by a licensed psychiatric hospital for the conversion to psychiatric beds of the psychiatric hospital's *beds of any licensure classification* shall be consistent with this Plan if the conversion does not increase the total licensed bed capacity of the psychiatric hospital. *(Emphasis added).*

"However, one or two providers have expressed concern that the language 'beds of any licensure classification' is overly broad. As such, we request the Cabinet to revise review criterion number 10 to address licensed tuberculosis beds and to state, more specifically:

> Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application by a licensed psychiatric hospital for the conversion to psychiatric beds of the psychiatric hospital's *licensed tuberculosis beds* shall be consistent with this Plan if the conversion does not increase the total licensed bed capacity of the psychiatric hospital. (*Emphasis added*).

"This would address SUN's concern regarding utilization of a licensure classification

whose time has come and gone."

(b) Response: The Cabinet has agreed to amend the State Health Plan; II. Behavioral Health Care; A. Psychiatric Beds; Review Criterion 10 as follows:

> Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application by a licensed psychiatric hospital for the conversion to psychiatric beds of the psychiatric hospital's licensed tuberculosis beds [~~of any licensure classification~~] shall be consistent with this Plan if the conversion does not increase the total licensed bed capacity of the psychiatric hospital.

KHA is supportive of this revision, which will allow SUN Behavioral Health Kentucky, the only facility with licensed tuberculosis beds, to convert the otherwise unserviceable beds of an outdated licensure category to psychiatric beds and improve access to inpatient psychiatric care in Northern Kentucky.

(7) Subject: Level II Psychiatric Residential Treatment Facilities, Bed Limit

(a) Comment: Three comments regarding the changes in the State Health Plan regarding Psychiatric Residential Treatment Facilities were received from Kentucky Hospital Association, Children's Alliance, and Purchase Youth Village. Those comments are included and summarized as part of this comment. (This comment relates to "II. Behavioral Health Care; B. Psychiatric Residential Treatment Facility; Review Criteria; Level II PRTF".)

1. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in strong support of the addition of Criterion 16 to provide that an application to establish PRTF Level II beds by an existing licensed Kentucky psychiatric hospital on the hospital's campus or through the use of existing space shall be consistent with this Plan. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated: "KHA has long advocated that psychiatric hospitals should be permitted to develop PRTF II beds on their campus to complement existing inpatient and outpatient services so that hospitals can offer a full continuum of care. This helps patients move smoothly from inpatient to resident to outpatient to home, while also providing the added benefit of having immediate access to inpatient services to address acute exacerbations if a patient's condition deteriorates and they require inpatient care."

He described the "critical need for the establishment of PRTF II beds", which is a level of care "developed to treat a targeted population of children ages four to 21 with a severe emotional disability along with severe and persistent aggressive behaviors, intellectual disability, sexually acting out behaviors, or developmental disability. The need for PRTF II services is particularly significant today in order to treat patients with these specialized needs and, particularly, aggression…

"Despite awarding CONs for the 145 allowable PRTF Level II beds, only one PRTF II facility has been established since 2010 when the law was enacted, and that facility just opened last year… Recently, KHA's Psychiatric and Chemical Dependency Forum has

made recommendations to the Cabinet on ways to improve the PRTF II regulations and reimbursement... If regulatory changes are made such that hospitals could develop PRTF II services in a financially feasible manner, the State Health Plan could stand in the way unless this change is made. Therefore, it is critical that this proposed exception to the bed cap be included in the Plan."

2. Comment: On behalf of the Children's Alliance, Michelle Sanborn, President, submitted comments in opposition to KHA's proposal, which was incorporated in the proposed 2018 Update to the State Health Plan. In her comments, Ms. Sanborn stated: "As amended, the 2018 Update to the 2017-2019 State Health Plan provides an exception to the PRTF Level II 145 Certificate of Need (CON) bed limit for licensed psychiatric hospitals, when the PRTF Level II beds will be on the hospital's campus or use existing space within the psychiatric hospital.

"The Children's Alliance strongly opposes an exception to the CON bed limit for one specific service type. The Children's Alliance does not understand why the state would establish exceptions to the CON process for the specific service type, and since they are considering making this exception, why they would not allow existing PRTF Level II facilities that are currently operating, to expand their services, versus establishing an exception to a specific 'service type' that is not currently operating this service. This exception would be extremely unfair to the agencies already providing PRTF Level II services and to all those agencies who applied for and spent an excessive amount of money and resources to obtain, or trying to obtain a CON for a PRTF Level II and were not awarded the CON. Given that there is a CON process and bed limit established, if more beds are needed, then the state needs to consider increasing the bed limit, not give an exception to a specific service type.

"Additionally, it should be noted that a psychiatric hospital already holds a CON for 24 PRTF Level II beds and this psychiatric hospital has not opened these PRTF II beds. Why would the state extend an exception to psychiatric hospitals when a psychiatric hospital is not using the CON beds that have been allocated through the established CON process? Why have a CON process and bed limit, if loop holes are going to be allowed around the process? This seems extremely unfair to other service types that are subject to the CON process."

3. Comment: M. Wasim Sajid, MD, Executive Director, Purchase Youth Village, Benton, KY, submitted comments addressing the proposed changes to the review criteria for PRTF Level II. Dr. Sajid stated: "As amended, the 2018 Update to the 2017-19 State Health Plan provides an exception to the PRTF Level II 145 Certificate of Need (CON) Bed limit for licensed psychiatric hospitals, when the PRTF Level II beds will be on the hospital campus or use existing space within the psychiatric hospital. SWIS Purchase, LLC dba Purchase Youth Village (PYV) is a 24-bed Level II PRTF in Benton, KY and so far it is Kentucky's first and only Level II PRTF. PYV have been providing psychiatric residential services successfully to children and adolescent in a 'home-like' setting for over a year now. We are about to open another such facility in Bardstown, KY in the very near future.

"Purchase Youth Village strongly opposes an exception to CON Bed limit for one specific service type. We do not understand why the specific service type (that is not

currently operating this service) gets the exception and we still have to abide by this regulation. SWIS Purchase, LLC will like to request more beds but can not apply for CON due to the bed limit. We specialize in this service type and are committed to meeting the needs of the state. Additionally, only one psychiatric hospital in Kentucky has so far applied for PRTF Level II beds. That hospital already holds a CON for more than 5 years and still has not opened these beds.

"This exception will be extremely unfair to agencies like ours who have spent an excessive amount of money and resources to obtain the CON and are already providing this service. If the state finds a need for Level PRTF II beds, increasing the bed limit would make more sense than giving an exception to a specific service type. SWIS Purchase, LLC will like to open more PRTF Level II facilities if the beds become available. We think that the CON process should be fair for all service providers and no loop holes should be allowed to favor any specific service provider."

(b) Response: The Cabinet appreciates the comments regarding the psychiatric residential treatment facilities. Since the close of the public comment period, the KHA and Children's Alliance have consulted and come to the agreement that the opportunity to provide PRTF Level II services should not be limited to existing licensed psychiatric hospitals. In agreement, the KHA and Children's Alliance have proposed a revision to the PRTF Level II review criteria deleting the 145 bed limit. The Cabinet agrees with this proposal and has included the deletion of the 145 bed limit in the revised State Health Plan. At this time, there is a need for PRTF Level II services in Kentucky. Although certificate of need authority has been issued for 145 beds, only 24 beds have been implemented and currently provide PRTF Level II services. Thus, there is a bed shortage. This amendment will remove one of the barriers preventing the delivery of much needed services.

(8) Subject: Level II Psychiatric Residential Treatment Facilities in Hospitals

(a) Comment: A comment regarding the changes in the State Health Plan regarding Psychiatric Residential Treatment Facilities was received from Heidi Schissler Lanham, Legal Director, Protection and Advocacy. The comment is included and summarized as part of this comment. (This comment relates to "II. Behavioral Health Care; B. Psychiatric Residential Treatment Facility".)

Heidi Schissler Lanham, Legal Director, Protection and Advocacy, commented regarding the proposed amendment that would allow licensed psychiatric beds to utilize existing capacity to provide PRTF Level II services. She stated that "Additional language should be added to the proposed change to reflect the statutory requirements in KRS 216B.457(2)." She proposed amending Criterion 16 to repeat the statutory requirements of KRS 216B.457(2), as follows:

> 16. Notwithstanding criterion 1, an application to establish PRTF Level II beds by a licensed Kentucky psychiatric hospital on the hospital's campus or through the use of existing space shall be consistent with this Plan <u>so long as they are located on a separate floor, in a separate wing, or in a separate building.</u>

(b) Response: The Cabinet appreciates the comment from Protection and Advocacy. In response to comments received and summarized under "(7) Subject: Level II Psychiatric Residential Treatment Facilities, Bed Limit", review criterion 16 has been removed from the State Health Plan for Psychiatric Residential Treatment Facility, Level II. Thus, the revision proposed by Protection and Advocacy cannot be made. The establishment of facilities to provide PRTF Level II services must comply with KRS 216B.457 and pursuant to KRS 13A.120, an administrative regulation shall not restate what is already prescribed by statute. Therefore, the revision is not needed as the purpose of the proposed revision is already being met.

(9) Subject: Post-Acute Skilled Nursing Beds in a Hospital

(a) Comment: The Cabinet received numerous comments regarding the proposed change in the State Health Plan to allow acute care hospitals to establish long term care services. The Kentucky Hospital Association submitted comments in support of the new criterion while the Kentucky Association of Health Care Facilities and LeadingAge as well as 18 nursing facilities submitted comments in opposition to the proposed criterion. The comments are included and summarized as part of this comment. (This comment relates to "III. Long-Term Care; A. Nursing Facility Beds; Review Criterion 5".)

1. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in strong support of the proposed changes to the State Health Plan, III. Long-Term Care; A. Nursing Facility Beds; Review Criteria 5. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated: "KHA commends the Cabinet for updating the language in criterion 5 as well as the addition of Specialized Long Term Care Beds. We appreciate that Cabinet officials have considered comments submitted by hospital members and by KHA in previous comment periods. We agree that the proposed changes address the communicated needs to expand the ability of hospitals to provide more timely and appropriate care for patients who no longer require acute care but do need to continue their care in a rehabilitative post-acute setting. As KHA has addressed in previous comments, there are growing challenges with placing a wide range of acute care patients in available, high quality skilled nursing beds which are able to meet their needs.

"One of these drivers is from the Centers for Medicare and Medicaid with implementation of several quality payment programs intended to increase quality of care and reduce cost. These programs are outlined below: 1. Hospital Readmissions Reduction Program; 2. Bundled Payment, 3. Accountable Care Organizations. Criterion 5 does well to address the readmission penalty challenge hospitals continually face. We thank the Cabinet for addressing these issues."

2. Comment: Elizabeth A. "Betsy" Johnson, President/Executive Director, Kentucky Association of Health Care Facilities/Kentucky Center for Assisted Living, submitted comments in opposition to proposed changes to Long Term Care review criteria. She

stated: "Our membership strongly opposes the proposed changes to 900 KAR 5:020 for three main reasons: (1) new nursing facility beds are not needed in Kentucky; (2) the addition of new nursing facility beds will only increase the deficit in the Kentucky Medicaid program; and (3) the addition of new nursing facility beds will decrease the quality of services that are provided. We also firmly believe that the proposal violates the separation of powers provision in the Kentucky Constitution and does not achieve the goals of the hospitals seeking the addition of new nursing facility beds." The letter then restated the provisions of the State Health Plan, III. Long-Term Care, A. Nursing Facility Beds.

"...it must be noted that the Kentucky General Assembly has already spoken on the Cabinet's attempt to add new nursing facility beds in Kentucky. The Cabinet's own Long-Term Care Bed Need Criteria shows that **every county** in Kentucky has a surplus of beds, except Clinton County... During the 2018 session of the Kentucky General Assembly, the legislature passed SB 123, with overwhelming bi-partisan support, to prevent the Cabinet from issuing a certificate of need for a new long-term care bed in any county that does not show a need for the service.'... This latest attempt by the Cabinet to add new long-term care beds is in direct conflict with legislative intent of SB 123."

Further, Ms. Johnson opposes the proposed review criterion 5 and describes it as "a reinvented Post-Acute Pilot Project that was overwhelmingly rejected by the General Assembly in SB 123. However, it goes one step further by limiting these short-term rehabilitation services to hospitals and excludes existing licensed skilled nursing facilities." Ms. Johnson requested that her Association be included in stakeholder discussions with the Cabinet related to post-acute services. Ms. Johnson made similar comments when she testified at the public hearing.

3. Comment: On behalf of LeadingAge Kentucky, a membership organization representing Long Term Care, Senior Living, and providers of services to the Intellectual and Developmentally Disabled, President Timothy L. Veno submitted comments on the State Health Plan. LeadingAge opposes the establishment of any new nursing facility beds and cites the nursing facility need calculation as showing an excess of 18,000 nursing facility beds in Kentucky. Specifically, LeadingAge opposes III. Long-Term Care; A. Nursing Facility Beds; Review Criteria 5. The comments predict that the addition of nursing facility beds will have "a detrimental effect on the existing long term care infrastructure and will erode quality significantly." The comments describe the history of the enactment, and later repeal, of a statute allowing dual licensure allowing hospitals to establish skilled nursing or intermediate care beds without a certificate of need when such beds were not available in the county where the hospital is located or where the patient resides, as well as subsequent legislation resulting in the establishment of 1,071 new nursing facility beds notwithstanding the certificate of need requirements. The comments also describe the federal program allowing smaller acute care hospitals to provide services in swing beds with that interchange between acute-care- or post-acute care and their respective reimbursement. In addition, the letter references Senate Bill 123 from the 2018 General Assembly, requiring the previously established post-acute transitional care pilot program to authorize the establishment of new nursing facility beds only in counties demonstrating a need for nursing facility beds per the state health plan need assessment. As an alternative to the proposed revision, LeadingAge suggests "good faith dialogue among Acute Care Hospitals and the Nursing Facility profession and finally

begin to match patients to Nursing Facilities that have proven metrics" and "appropriate capabilities to lower readmissions."

4. Comment: Teresa Kiskaden, Bluegrass Health Partners, submitted a comment in opposition to revisions to the State Health Plan that will allow for the addition of nursing facility beds. She stated: "There is not a need for additional skilled nursing facility beds in Kentucky. Current providers are more than capable of meeting the needs for long term care services in Kentucky. The majority of facilities currently licensed to provide skilled nursing services in Kentucky are caring for patients with diagnoses of heart failure, pneumonia, chronic obstructive pulmonary disease, urinary tract infections and myocardial infarctions. As skilled nursing facilities are not experts in acute care neither are hospitals experts in post-acute care. Patients who need post-acute care services should be cared for in high quality low cost settings not in a hospital."

5. Comment: Lanna Roberts, Parkview Nursing and Rehabilitation Center, Consulate Health Care; Maribeth Shelton, Administrator, Cumberland Valley Manor; Truly Pennington, BSN, RN, Administrator, Grand Haven Nursing Home; Kim Gibbons, Hicks Golden Years Nursing Home; Ruby Pigman, Knott County Health and Rehabilitation Center; Jessica Hall, Director of Nursing, Knott County Health and Rehabilitation Center; Emily Jones-Gray, Administrator, Mountain Manor of Paintsville; Tom Davis, Administrator, Diversicare of Nicholasville; and Jonathan McGuire, Administrator, Greenwood Nursing and Rehabilitation Center, submitted comments expressing opposition to the amendment to 900 KAR 5:020 and stating that there is not a need for additional skilled nursing facility beds in Kentucky, that licensed skilled nursing facilities are currently meeting the needs for long-term care services in our state, that acute care hospitals are not post-acute experts and should not be taking the role as such, and that short-term rehabilitation patients should be cared for in the high quality setting of a licensed, lower cost, skilled facility instead of a hospital.

6. Comment: Jason Gumm, Administrator, Diversicare of Glasgow, submitted a letter stating opposition to the revision to the long-term care review criteria allowing hospitals to provide short term post-acute care. Mr. Gumm stated that the proposal would be damaging to Medicaid and does not address difficult to place patients. Further, Mr. Gumm stated that the Commonwealth is not using existing state resources like Eastern State Hospital for placement of difficult to place patients. Mr. Gumm added that the State Health Plan need calculation indicates there is no need for additional long term care beds. Mr. Gumm noted that he is confused by the concept of short term stays for long term care patients and that removing short stay patients from long term care centers would be financially devastating to existing business owners. Mr. Gumm stated that the proposal lacks penalties or accountability for approved programs to meet the state health plan requirements and describes the proposal as bad policy.

7. Comment: John Dailey, President, Management Advisors Inc., Forcht Group, emailed comments opposing revisions to review criteria impacting skilled nursing facility beds and stating that in 119 of Kentucky's 120 counties the need methodology demonstrates no need for additional beds and that the proposal will not improve the health

and well-being of the long term care population.

8. Comment: Melodie G. Bingham, CPA, Hargis and Associates, LLC, and Rhonda Houchens, Director of Operations, Hargis and Associates, LLC, submitted comments as accountants and consultants for the long term care industry and stated there is no need for additional skilled nursing facility beds in Kentucky. They also objected to hospitals' ability to deliver post-acute care. They stated that the proposal would further strain the Medicaid budget and ignores the long term care need calculation. They concluded by suggesting that the proposal would discourage nursing facilities from continuing to operate in Kentucky if hospitals are allowed to "manipulate Medicare and Managed Care reimbursement away from Nursing Facilities."

9. Comment: Tevis Tuggle, MBA, RN, LNHA, Administrator, Landmark of Lancaster Rehabilitation and Nursing Center, submitted a comment in opposition to revisions to 900 KAR 5:020. His email states: "Currently there is not a need for additional skilled nursing facility beds in Kentucky. Landmark of Lancaster and the many other licensed skilled nursing facilities are meeting the needs for long-term care services in Kentucky. Acute care hospitals are an extremely important division of healthcare in Kentucky. But acute care hospitals are not post-acute experts. In the hospital setting you will be provided skilled nursing care and therapy as needed. After therapy/treatment you will return to a hospital bed in your hospital room. In a skilled nursing facility, our goal is to not only provide therapy and skilled nursing care, but also involve you in the activities and skills you will be doing in your home. Yes, you will get therapy by a therapist and medications from a nurse just like the hospital, but you will also be encouraged to go on outings, participate in activities, eat in the dining room, help with your care, go on a home visit with a therapist, and more. Skilled nursing facilities have been successful in providing short-term rehabilitation to patients for years and have become the experts in inpatient, post-acute rehabilitation."

10. Comment: Regina Lyons, Administrator, Landmark of River City, submitted an email stating that the facility was not in favor of changing the certificate of need process and that "it has worked well for many a year."

11. Comment: Susan Arnold, Management Advisors, Inc., Forcht Group, submitted the following comment: "I have been a Nursing Home Administrator in Kentucky for the past 32 years, and currently am employed by Management Advisors working with nine nursing facilities in Eastern Kentucky. I strongly oppose the amendment to 900 KAR 5:020 and do not feel there is a need for additional skilled nursing facility beds in Kentucky at this time. There are adequate high quality providers of long term care in our state. I daily see excellent outcomes from short term rehabilitation providers in nursing facilities, I also see many residents with complicated clinical care being provided excellent care in a homelike settings. Practically speaking, I do not see that our state has the workforce available to staff additional beds. The majority of healthcare providers compete fiercely for their clinical staff. Please reexamine this proposal as it is not feasible for our state at the present."

12. Comment: Rick Hendrickson, Administrator, Redbanks Colonial Terrace Nursing Home, submitted comments in opposition to revisions allowing for the addition of nursing facility beds. He said: "I am in opposition to additional nursing home beds, without the CON process. This can packaged in many ways, but the fact remains, we do NOT need additional beds of this type, as there is a surplus of beds statewide. The CON process is in place for a reason. By allowing this without CON, it opens the door for more attacks on long term care. We are struggling anyway, with finances, revenue and regulation. We do NOT need the added challenge of a process without CON that will add unneeded bed capacity. The facts support my opinion."

13. Comment: Shelley Laneve, RN, BSN, Long Term Care Administrator, Shemwell HealthCare owner, submitted the following comments in opposition to review criteria allowing for the addition of nursing facility beds: "Please reconsider the possibility of adding long term care beds in the state of Kentucky. Many facilities in our area are struggling with low census without adding 'fuel to the fire'. I'm sure this is being considered to benefit someone but as I understand the data, this is not a good choice for those operating in the state as a whole."

14. Comment: Brian K. Jaggers, Administrator, Somerwoods Nursing and Rehabilitation, submitted the following comment: "The Residents, Owners, Administration and Caregivers of Somerwoods Nursing and Rehab vehemently OPPOSE the proposed amendment to 900 KAR 5:020. Somerset, Pulaski County as well as the entire Lake Cumberland Development District are well served by the current model of Acute Care Hospitals, Regional Hospitals, Skilled Nursing, Personal Care, Assisted Living, Home Health and Outpatient Rehabilitation facilities...The facilities in this area are each committed to providing quality rehab care to the citizens in the community. This care is provided in an efficient manner and within a continuum of care approach... If passed, this amendment will detrimentally change the skilled nursing and custodial care provided to more than 30,000 Kentuckians each and every day. It will also create fiscal inefficiencies in the more than 300 Skilled Nursing facilities serving Kentuckians as well as thousands of other physician practices, pharmaceutical, home health, rehabilitation companies, etc... which function well under the current model..."

Accompanying Mr. Jaggers' letter, he attached additional letters and emails from employees of Somerwoods Nursing and Rehab, also in opposition to the amendment. The names of those commenters and a summary of their letters are included as "Comment 17." of this subject item.

15. Comment: Terry L. Skaggs, CFO and owner, Wells Health Systems, and Chairman of the Board of the Kentucky Association of Health Care Facilities (KAHCF), commented addressing the review criteria for long term care beds: "Thank you for allowing me to comment on the proposed amendments to 900 KAR 5:020. My name is Terry Skaggs. I am an owner and Chief Financial Officer of Wells Health Systems in Owensboro. We own two facilities in Western Kentucky and represent fourteen facilities that we have consulting relationships with throughout the Commonwealth. I am also the Chairman of the Board of the Kentucky Association of Health Care Facilities (KAHCF). KAHCF represents over 200 long-term providers in Kentucky. On behalf of our facilities

and the membership of our Association, I want to thank the Cabinet for giving me the opportunity to address the proposed changes to the state health plan. The Cabinet's LTC Bed Need Criteria shows no documented need for additional nursing facility beds in the Commonwealth – except Clinton County, which shows that 8 beds are needed to serve that county. The proposed amendments clearly conflict with the Cabinet's own data.

"Last year, I testified regarding proposed changes to the state health plan. At that time, I addressed the concern that the Cabinet had ignored its own data when making changes to the state health plan. Even now, additional nursing facility beds are not need in Kentucky. With statewide occupancy well below 90%, there is adequate capacity to meet the long-term care needs of Kentucky residents.

"This past legislative session, the Kentucky legislature dealt with this issue. The Kentucky General Assembly passed SB 123 with overwhelming bipartisan support to prevent the Cabinet from issuing a certificate of need for a long-term care bed in any county that does not show a need for the services. Once again, though, we are submitting comments addressing proposed changes that would add beds. Again, as stated previously, there is no need for additional long-term care services in Kentucky. Nothing has changed since the legislature addressed this issue. The Cabinet's proposed changes ignores the will of the Kentucky General Assembly.

"There is a need to address the concern of one rural hospital, but the proposed amendments have taken that specific issue to a broader spectrum. The proposed amendment for additional nursing facility beds, in general, runs contrary to SB 123 that was passed during the 2018 Kentucky General Assembly, as previously stated.

"Additionally, these proposed changes will have a significant financial impact to the already overburdened Medicaid budget, which is facing a $300 million shortfall over the next two years. These numbers were shared directly with leaders from our profession by Secretary Meier and former Medicaid Commissioner Steve Miller in a June meeting. Additional beds will further burden the Medicaid program.

"In summary, I respectfully request that the Cabinet remove the proposed changes to the long-term care section in the state health plan."

16. Comment: Jay M. Frances, CEO, Owner, Legacy Health Services, Inc., commented that, along with his partner, he owns and operates three long term care facilities in Kentucky (Brighton Cornerstone in Hopkins County, Pioneer Trace in Fleming County, and Cambridge Plane of Fayette County). He is strongly opposed to the amendment in 900 KAR 5:020. He stated: "...it is an understatement to say that there is no need for additional skilled nursing facility beds in this state as all of the data supports this. Our current licensed skilled nursing facilities in this state have been serving the communities for years, both in long term needs as well as short term rehab needs. Unlike the hospitals that continue to push for this amendment, we have continued to prove to lawmakers in Kentucky that our facilities can, and will continue to, care for those patients' needs in a high-quality, low cost setting. These hospitals cannot make this claim, nor can they effectively justify the issuing of additional CONs when all of the supporting data shows yet again that there is 'no need' for such beds."

17. Comment: Representatives from several nursing and rehabilitation centers submitted identical comments in opposition to the post-acute skilled nursing beds

proposal in the State Health Plan.

Letters were received from the following representatives of the Mountain View Nursing and Rehab Center: Russell Lambert, Vivian Lambert, Terri McDowell, Courtney Cinnamon, Ann Sexton, Rose Aldridge, Yolanda Salas, Linda Webb, Sindy Brock, Mary J. Balkins, Christina Marsle, Dannie Brock, Hattie Rice, Brittany McGreger, Karen Tigre, Matthew Farme, Pansy Scott, Jamie Collett, April Sexton, Marie Tresure, Sandy Baker, Mitzy Oneski, Teresa Miracle, Brenda Watts, Lena Brock, Merle Middleton, Christal Nina, Lauren Ausmus, Sherry Epperson, Robert Britton, Jeannie M. Cox, Tracy Hensley, Kathy Hoskins, Heather Ann Partin, Brodie Erwin, Shelly Johnson, Rodney Elliott, Savannah West, Melanie Lewis, Taylor Woodward, Betty Miracle, Christy Saylor, Lena Goodin, Amy Elliott, Kimberly Gambrel, Sherry Gray, Baleli Tuttle, Kathy Miller, Jessica Miracle, and Heather Pocti. Additional letters were received from two (2) Mountain View representatives, but the signatures were not legible.

Letters were received from the following representatives of Tri-Cities Nursing and Rehabilitation Center: Rachel Lunford, Angel Harrell, Lori Hodge, Donna Repperson, Mitzi Huff, Ann Epperson, Pam Raleigh, Kendra Nortl, Ginger Turner, Vickie Fortets, Marsha Powers, Mary Beth Craig, Jessica N. Lewis, Kristi Whitehead, Sarah Hinkle, Terenia Bledsoe, Mary Combs, Tonya Turner, Jeff Wilder, Ashly Page, Ginger Fletcher, Brittany Baily, Sharon Ison, Della Baker, Heather R. Huff, Lamborghini Greene, April Kidwell, Teresa Turner, Tiffany Harris, Janel V. Adams, Heather Ewing, Kayla Lewis, Trena Ison, Dorothy Smith, and Christy Roark. Additional letters were received from four (4) Tri-Cities representatives, but the signatures were not legible.

Letters were received from the following representatives of Rivers Edge Nursing and Rehabilitation Center: Diane Rabourn, Kathryn Allen, Michael Klomp, Allin Maupin, Megan D. Wallmans, Brian M. Murphy, Carrie Moore, Lisa Hughes, Marilyn Malone, Erin Farley, Heather Lilly, Earnestine Winbush, Sharese Sanders, Faith Robinson, Karen Gilbert, Samantha Kirman, Pam Peerce, Matthew McMichael, Frank Anthony, Janice Sanford, Lozetta Marie Rison, Joshua P. Wesley, Kelly Curtis, Deborah J. Posey, Brittany Kellogg, Edward Bennett, Victoria Wenzel, Tracy Gatt, Mary Beich, Jackie Carlin, Michele Baugh, Chelsea Hall, Donna Hoffs, Jerushia Goodlett, Bobby Jones, Annette Sidney, Sherry Brown, Tabitha Andrews, Rudy Shelley, Sharon Polloch, Ralph Matthis, Donald Kern, and Colleen Smith. Additional letters were received from sixteen (16) Rivers Edge representatives, but the signatures were not legible.

Letters were received from the following representatives of Greenwood Nursing and Rehab Center: Hailey Fritz, Sheena Dickson, Ashley Brown, Susie Korfits Broch, Ronda Wright, Nancy Parsley, Seth Denton, Lisa Smith, Dana R. Bird, Elisa James, Tammy Forgy, Bethann Daugherty, Kayla Burton, Ellen P. Staller, Melissa Bouldin, Richard Brannon, Kate Bradley, Kimberly Walker, Cynthia Sarazin, Sherri Jones, Linda McMurphy, Bonnie Fleischman, Donita Brown, Maureen Brackshaw, Helen Corley, Rebecca Lyne, Mendi Willis, Jane Huff, Melody Lawson, Vickie Ramjon, Abby Flint, Amanda Steffly, Connie Stamper, April Smith, Donna Haycraft, Brandi Blanchard, Pine Ruby, Toya Boards, Chrissy Laz, Julie Hunt, Shelia Minnicks, Cory Wilkins, Robert McClintock, Teresa Steinbergen, Debi Davis, Amanda Keller, Roxanne Nordike, Amy Dye-Spann, Amanda Drone, Michelle Cline, Connie Parker, Teri Elrod, Kimberly A. Stevens, and Kathleen Warren. Additional letters were received from twenty-eight (28) Greenwood representatives, but the signatures were not legible.

Letters were received from the following representatives of Lake Way Nursing and Rehab: Tammy Crittenden, Lisa Duncan, Angela Reaves, Buddy Price, Heather Gamble, Molly LaVerdi, Madonna Edwards, Tiffany Hayden, Ashley Dixon, Suzanne Lewis, Kathy Morehead, Melissa Price, Ellen Warren, Tia Collins, Teresa Brasher, Sylvia Jestes, Tatum York, Carlia Tazmen, and Melissa Mitzy.

A group letter submitted on behalf of Principle Long Term Care's skilled nursing facilities was submitted. The letter was signed by the following eight administrators: Jonathan McGuire, Greenwood Nursing and Rehab Center; Robert Flatt, Essex Nursing and Rehab Center; Jackie Carlin, Rivers Edge Nursing and Rehab Center; Vivian Lambert, Mountain View Nursing and Rehab Center; Tammy York, Lake Way Nursing and Rehab Center; Brian Jaggers, Somerwoods Nursing and Rehab Center; Doris Ecton, Johnson Mathers Nursing Home; and Jeff Wilder, Tri-Cities Nursing and Rehab Center.

Letters were received from the following representatives of Somerwoods Nursing and Rehab Center: Danielle Pence, Tonia Miller, Daniel Parker, Nakkita Ard, Ailsa Judd, Kathy Tucker, Melissa Strink, Amber Hoskins, Jay Hall, Frances A. Evans, Stacey J. Bates, Tonya Reynolds, Tamara Kingsley, Surey M. Brooks, Teresa Matthews, Sylvia McCormick, Lisa G. Brown, Leslie Barrett, Tyler Baker, Chelsea King, Emanuel Leacy, Kayla Adams, Karen Bunch, Brenda Worley, Francis Hines, Tiffany Huff, Dan Helm, Mesha McIntosh, Brittany Williamson, Samy Cald, Rosa Pruitt, Jessica Slone, Elisi Phelps, Tiffany Cook, Wanda Rose, Brittany Collier, Angel Meece, Misty Campbell, Rosemary Cross, Jennifer Baker, Billie Bune, Kelai Ragan Miller, Kimberly Decker, Virginia Ramsay, Caitlyn Amkrite, Dina C. Lay, Lindsey Bowling, Stephanie Dick, Brandon Row, Deborah Godby, Tiffany McKillen, Robbie Ramsey, Lisa Boyd, Beth M. Quinn, Peggy Holden, Heather Hammer, Crystal Thurman, Patricia B. Dean, Craig C. Wesly, Carolyn L. Bruhn, Patty Murphy, Meredith Surber, Phyllis Hunt, Jacob L. Scott, Clara Begley, Violet Rose, Jennifer Gregory, Jean Kemper, Kaitlyn Shut, Sarah Lay, Amanda Gretz, Donna Gray, Jamie Saunders, Ashley Harris, Mary G. Whitens, Angel Ward, Diane Rose, Dora Buster, Kathy Cook, Calli Thomas, Bethany Overly, Jessica Stacey, Angela Anshear, and Pat Knapp. Additional letters were received from fifteen (15) Somerwoods representatives, but the signatures were not legible.

The letters stated that the nursing homes provided positive benefits to the communities and faced unique challenges in a highly-regulated environment. The proposed amendment "would fundamentally, and detrimentally, reshape the skilled nursing care industry in Kentucky. The net impact would likely be the economic undermining of high-quality community-based SNFs that care for the Commonwealth's most vulnerable residents: the 65+ population of limited financial means.

"This assessment is not hyperbolic. As proposed, this amendment would enable acute care providers (hospitals) to establish 'specialized long term care bed' units to serve short-term rehabilitative patients without the same government regulation that apply to SNF's. The distinction between 'long term' and 'short term' is an important one. Community-based, freestanding SNFs serve both types of patients. In fact, they depend on a balance of long- and short-term residents to operate efficiently. In order to serve the means-limited 65+ population who require long-term care for complex chronic conditions, a reasonable balance of reimbursement must be available. Through no fault of their industry, reimbursement for SNF services is, in most cases, insufficient to cover operating expenses without a diverse blend of patients. If hospitals are able to establish specialized

units for short-term patients only, they will not face the same reimbursement challenges that their freestanding, truly 'long-term' care providers do. In fact, many hospitals rush to return the LTC patients back to the SNF's just because the reimbursements are so low and it seems ... they only want the high reimbursement short term patients to shore up their bottom line, essentially cherry picking the patients that are the most profitable while leaving the SNF's with the sickest, most time intensive patients to care for. Instead of proven community-based SNFs continuing to serve the entire post-acute population, a majority of short-term rehabilitation patients will be diverted to these proposed new beds for which there is no evidence difference care outcomes will be realized. Many freestanding SNFs... already demonstrate a commitment to quality care and outcomes.

SNFs "currently work diligently to develop partnership with acute care providers. We are abundantly aware of the changing healthcare reimbursement landscape that continues to push for mechanisms to reduce re-hospitalizations. We strive daily to refine our systems to continuously improve our outcomes. SNFs are sophisticated members of the post-acute landscape and we are fully capable of providing the rehabilitation services the proposed amendment to the State Health Plan identifies. We are 'subject matter' experts and, unlike the acute care providers who largely exited the SNF industry years ago, we remain committed to the entire population in need of our services.

"For those of us experienced in this industry, we recognize the underlying intent of this proposed amendment that targets high-reimbursing patients and does nothing for the larger number of individuals who require complex care for chronic conditions. Formally codifying the amendment would be catastrophic, not just for the wide network of community-based, freestanding SNFs, but for the entire 65+ population in Kentucky."

(b) Response: The Cabinet appreciates the comments regarding post-acute skilled nursing beds in hospitals. The Cabinet will amend the proposed State Health Plan to remove Criterion 5 so that the State Health Plan does not include a provision allowing qualified hospitals to add long term care beds. Instead, the Cabinet will continue to engage stakeholders to better understand the needs of patients in the long term care setting and work to improve access to quality care through alternative methods if appropriate.

(10) Subject: Specialized Long Term Care

(a) Comment: The Cabinet received seven comments regarding the proposed change in the State Health Plan to allow licensed acute care hospitals and nursing facilities to establish specialized long term care services without demonstrating consistency for the traditional long term care need assessment. Specialized long term care was defined to be a program of care for patients who require technically complex treatment with life supporting equipment or who have serious problems accessing appropriate skilled nursing care due to the specialized treatment required by their diagnosis and level of functional limitations. The new criterion was precipitated by comments and information submitted by Rockcastle Regional Hospital, which, in addition to providing hospital services, provides skilled nursing care to ventilator dependent patients. Rockcastle Regional Hospital responded to the new criterion by requesting that it be limited to emergency circumstances acknowledged by the Cabinet. The Kentucky Hospital

Association submitted comments in support of the new criterion. The Kentucky Association of Health Care Facilities, LeadingAge, and Baptist Life Communities, as well as Jason Gumm, Administrator, Diversicare of Glasgow, and Jay H. Trumbo, Health Systems of Kentucky, LLC, submitted comments in opposition to the proposed criterion. The comments are included and summarized as part of this comment. (This comment relates to "III. Long-Term Care; A. Nursing Facility Beds; Review Criterion 6".)

1. Comment: On behalf of Rockcastle Regional Hospital and Respiratory Care Center ("Rockcastle"), Stephen A. Estes, President/CEO, submitted comments requesting revision to the proposed criterion included in the draft State Health Plan for specialized long-term care. Mr. Estes wrote the following: "...I am writing to urge the Cabinet for Health and Family Services ('Cabinet') to reconsider our prior request to amend the State Health Plan ('SHP') review criteria for nursing facility beds to reflect consistency with the SHP for CON applications to add beds when an emergency situation exists. While we appreciate the Cabinet's responsiveness to our initial request by proposing Criterion 6 be added to the Nursing Facility Bed portion of the SHP, we believe Criterion 6 may be overbroad and could lead to the unnecessary duplication of healthcare services. We believe a need exists in these types of circumstances for the Cabinet to have an opportunity to consider and determine the scope of an emergency circumstance so that a CON applicant cannot provide services that reach beyond the scope that is necessary to alleviate the emergency. Additionally, since this amendment will allow ventilator dependent providers to alleviate emergency circumstances beyond a temporary period, this amendment is necessary to improve Kentuckian's access to health care services.

"Emergency circumstances can arise due to factors not recognized by the current SHP methodology. For example, the current SHP methodology for calculating need does not consider factors that limit nursing facility bed availability that are solely used for ventilator-dependent services. This distinction is exceptionally important to Rockcastle due to its history of providing ventilator services. Since 1980, Rockcastle has served ventilator-dependent patients in its acute care hospital and respiratory care center and currently provides long-term care for patients that meet the certification requirements for operation of a ventilator-dependent unit pursuant to 907 KAR 1:022. Rockcastle receives ventilator referrals from across Kentucky for patients with health concerns ranging from spinal cord injuries to genetic birth defects and neurological diseases. In addition, Rockcastle is experiencing increased admissions as a result of the opioid epidemic including patients that are recovering from overdoses, from the effects of misuse of opioids, and from injuries often caused by opioid impairment. Rockcastle's patients are directly transferred to its ventilator unit from the intensive care units ('ICUs') of hospitals throughout Kentucky, including UK HealthCare.

"Rockcastle is currently the only provider of long-term nursing facility services for ventilator-dependent patients in Eastern or Central Kentucky. Rockcastle operates the only distinct part unit for ventilator-dependent patients certified to participate in Kentucky's Medicaid program pursuant to 907 KAR 1:022. Unfortunately, Rockcastle operates 127 skilled nursing facility beds and these beds are currently 100% occupied. Accordingly, there is an emergency basis for Rockcastle to add ventilator dependent beds in order to accommodate this ongoing emergency.

"Moreover, the majority of nursing facility beds in Kentucky are in semi-private rooms,

meaning nursing facility rooms are shared by more than one resident. In addition, as a matter of privacy, rooms can be shared only by residents of the same gender, and a bed's location in a semi-private room limits, by gender, which patients qualify for its occupancy. In other words, an unoccupied bed in a female resident's room is only available to a female patient and vice versa. Thus, while the SHP methodology might indicate a certain number of unoccupied beds, in reality, those beds might not be available to every potential resident. Furthermore, due to room sharing limitations and the current SHP methodology for determining need, a nursing facility often has both available beds and a waiting list of residents waiting for bed availability. This scenario facilitates the conundrum in which there is an urgent need for services but the same services are not approvable under current SHP methodology.

"The current SHP methodology does not consider the dedication of certain beds to special care, which also reduces the actual availability of beds, in its calculation of need. This creates a significant need for services in some service areas, as nursing facility beds dedicated to special care are not available to members of the general nursing facility population. For example, only nursing facility patients requiring certain respiratory treatments qualify for beds dedicated to ventilator-dependent patients. Because the SHP's methodology does not distinguish between beds available for the general nursing facility population and beds available for only qualified patients, the SHP's determination of need does not accurately reflect the number of beds available in a service area. Thus, again, a service area may need nursing facility beds even though the SHP methodology indicates otherwise.

"Ventilator-dependent patients create a special need for health services in Kentucky. With Rockcastle having dedicated itself to serving this special population, we encounter patients daily who become ventilator-dependent due to either medical or surgical reasons and cannot be dismissed from the intensive-care unit ('ICU') because of the need for mechanical ventilation. Most physicians are reluctant to transfer such patients to a general medical area in the hospital because of the lack of personnel with appropriate airway care and ventilator management skills. Further, these patients cannot be transferred to a traditional nursing facility because those facility does not have the proper equipment or specialized training it takes to provide ventilator-dependent patients of all ages. This is an exceptionally important point because many of Rockcastle's patients are pediatric and under 65. Traditional nursing facilities are simply not equipped or trained to provide ventilator-dependent care. Because of this factor and the lack of adequate reimbursement incentives, most skilled-care nursing facilities (SNFs) have been unwilling to accept these patients, although this situation is beginning to change in some areas of the United States. Thus, ventilator-dependent patients have had few alternatives to remaining in the ICU.

"New York State faced a similar problem in proving appropriate and quality healthcare services to patients who were ventilator-dependent. In fact, due to this unique situation, New York State developed specific program regulations to allow for nursing homes who specialize in ventilator-dependent care to establish programs and/or add beds to their existing facilities. The criteria set forth by New York is as follows:

> *A ventilator dependent resident is one who has been admitted to a Skilled Nursing Facility on a ventilator or has been ventilator dependent within five days prior to admission to the SNF. Patients*

who are in the process of being weaned off of ventilator support will qualify for this category for one month after extubation if they are receiving active rehabilitation services during that period. Residents in the facility who decompensate and require reintubation also qualify for this category.

"New Jersey also has a similar certificate of need process for these special care beds. In fact, they have developed regulatory requirements for obtaining a certificate of need for a Specialized Long-Term Care Bed for Ventilator Care. Those beds are defined as:

'Specialized long-term care' means a program of care provided in licensed long-term care beds for residents who require technically complex treatment with life supporting equipment or who have serious problems accessing appropriate nursing home care due to the specialized treatment required by their medical diagnoses and level of functional limitation.

"Currently in Kentucky, the only way a nursing facility can address a need for nursing facility beds that is not recognized by the current SHP methodology is pursuant to 900 KAR 6:080, the administrative regulation authorizing a health service provider to alleviate an emergency without first obtaining a CON. This regulatory authorization to provide emergency services is limited, however, and should the emergency circumstances continue beyond thirty days, the service provider must apply for a CON. If the CON is denied, the provider must cease the services alleviating the emergency and the emergency often resumes. The existing regulatory scheme is defective in its circularity, as for some service areas, nursing facility care is accessible to residents only temporarily—from the time the Cabinet is notified of an emergency until the unavoidable denial, due to the SHP, of the CON necessary to continue to provide the same services. Thus, circumstances surrounding a service area's need for nursing facility services may constitute an emergency and a facility may be authorized to provide services to alleviate the emergency even though a CON authorizing the provision of the same services is impossible to obtain.

"Rockcastle receives referrals from across Kentucky for patients with health concerns ranging from spinal cord Injuries to genetic birth defects and neurological diseases, and require mechanical ventilation. These ventilator-dependent patients are directly referred from the ICU of hospitals throughout Kentucky including UK HealthCare. Because the beds in these ICUs are being occupied on a long-term basis by ventilator-dependent patients due to the shortage of long-term ventilator-dependent NF beds, hospitals are facing crisis situations as well. Essentially, the lack of beds for these special needs patients has created a systemic crisis and emergency that Is particularly problematic for UK HealthCare as the state's largest Level IV trauma center. Because its ventilator-dependent beds currently operate at full capacity and other providers in its service area are unable to provide the complex services required by these high acuity, long-term ventilator-dependent patients, a need for additional NF beds dedicated for long-term ventilator-dependent patients exists.

"Since the SHP may preclude the Cabinet's approval of a nursing facility's application for a CON to add nursing facility beds when the addition of nursing facility beds is, in fact, needed, Rockcastle requests the Cabinet amend the SHP to allow for a current nursing facility provider to apply for nursing facility beds restricted to the limited purpose of

alleviating an emergency specific to ventilator dependent patients that require long-term ventilator services. As such, Rockcastle requests the Cabinet add the following provision to the SHP review criteria for nursing facility beds:

...

5. Notwithstanding criteria 1, 2, 3, and 4, and the above criteria, an application submitted by an existing facility that has met the emergency circumstances provision as outlined in 900 KAR 6:080, Section 2 and has received notice from the Office of Inspector General that an emergency exists shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating an emergency specific to ventilator-dependent patients that require long-term ventilator services.

"Amending the SHP to allow a facility to provide ventilator-dependent services to alleviate emergency circumstances is critical to the CON program achievement of improved access to healthcare. As written, 900 KAR 6:080 already includes safeguards that limit the provision of emergency services to the relieving of an actual emergency. Moreover, in notifying the Cabinet of the emergency, the administrative regulation requires that the provider include proof that all other area providers that are licensed to provide the health service at issue are aware of the emergency and have either refused to or are unable to alleviate the emergency. In other words, the provider of services pursuant to 900 KAR 6:080 is the provider of last resort. Furthermore, revising the SHP so that providers of ventilator-dependent services will not jeopardize the CON Program's purpose of preventing the duplication of services. Rather, allowing the provider of emergency services to obtain the CON necessary to completely alleviate an emergency would address needs unaccounted for in the current SHP and reduce the occurrence of future healthcare emergencies."

2. Comment: Jason Gumm, Administrator, Diversicare of Glasgow, submitted a letter stating opposition to the revision to the long-term care review criteria for specialized long-term care beds. Mr. Gumm stated that the exemption for hospitals to establish specialized long term care is not needed because the LTAC hospitals are already capable of providing the proposed service through a different licensing mechanism. Further, Mr. Gumm stated that he is not aware of any data to support the proposed service, that the language was too vague, and that the addition of the proposed service would negatively impact the Medicaid budget.

3. Comment: Jay H. Trumbo, Health Systems of Kentucky, LLC, submitted comments opposing the proposed review criteria for Specialized Long Term Care stating that there is currently no need for additional nursing facility beds, and there is excess capacity, lack of tort reform, rising costs of nursing labor, increasing health insurance costs for employees, runaway liability insurance costs and only miniscule increase in Medicaid reimbursement—all of which make operating a nursing facility in Kentucky very difficult. Mr. Trumbo cited recent bankruptcy filings by providers and that the problems should be addressed with tort reform and expanding provider tax. Mr. Trumbo also criticized the proposal as lacking quality requirements and not having fixed time limited or mandatory outcomes.

4. Comment: Elizabeth A. "Betsy" Johnson, President/Executive Director, Kentucky Association of Health Care Facilities/Kentucky Center for Assisted Living, submitted comments on behalf of the Association. She stated that "After discussions with Rockcastle Regional's legal counsel, the Association respectfully requests that the Cabinet amend the proposed changes to the state health plan to allow for a current nursing facility provider to apply for nursing facility beds restricted to the limited purpose of alleviating an emergency specific to ventilator dependent patients that require long-term ventilator services. The Association supports Rockcastle Regional's efforts in serving ventilator dependent individuals in Kentucky. For these reasons, the Association requests the Cabinet remove the current proposed language and add the following provision to the state health plan review criteria for nursing facility beds:

5. Notwithstanding criteria 1, 2, 3, and 4, and the above criteria, an application submitted by an existing facility that has met the emergency circumstances provision as outlined in 900 KAR 6:080, Section 2 and has received notice from the Office of Inspector General that an emergency exists shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating an emergency specific to ventilator-dependent patients that require long-term ventilator services.

"The Association believes that this will address the issues raised by Rockcastle Regional ... but not create unnecessary and duplicative health services in Kentucky, which will only increase the costs to the Kentucky Medicaid program.

5. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in support of the inclusion of the specialized long term care beds category. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated that KHA commends the Cabinet for the addition of Specialized Long Term Care Beds and states that inclusion of the category "addresses more specific and complicated challenges our hospitals continue to report... hospitals are increasingly challenged with placing medically complex patients, patients with behavioral diagnoses, obese patients and substance abusers in appropriate long term care settings. We believe that the development of this new category is a great first step to address these challenges, especially for patients needing long term ventilator care."

His letter also suggested that the Cabinet form a work group including stakeholder representatives to meet and develop "a comprehensive plan to address the health care availability deficits though CON, licensure and, importantly, adequate payment mechanisms under Medicaid to address the specialized or complex patients which are difficult to place and care for."

6. Comment: On behalf of LeadingAge of Kentucky, a membership organization representing Long Term Care, Senior Living, and providers of services to the Intellectual and Developmentally Disabled, President Timothy L. Veno submitted comments on the

State Health Plan. He said that LeadingAge opposes the establishment of any new nursing facility beds and cites the nursing facility need calculation as showing an excess of 18,000 nursing facility beds in Kentucky. In opposing the revision recognizing Specialized Long Term Care, the letter states that "any Nursing Facility is authorized under its existing license to provide Specialized Long Term Care services" and that there are existing reimbursement methodologies incentivizing the provision of it. LeadingAge argues that there is not a need for a revision to the State Health Plan to allow additional nursing facility beds.

7. Dr. Robert H. Long, President and CEO, Baptist Life Communities, submitted comments in opposition to the proposed review criteria allowing the establishment of long term care beds for Specialized Long Term Care programs. He stated: "As you are aware, the proposed amendment to the state health plan would allow licensed Kentucky hospitals to establish 'specialized' long-term care facilities by adding a new definition and associated requirements in the State Health Plan. BLC, along with many within the long-term care industry, has three main concerns about the proposed policy.

"1. We believe the proposed policy will put current KY licensed long-term care facilities at a strong competitive disadvantage. Hospitals often handle patient referrals to long-term care facilities. In the scenario outlined in the proposed amendment hospitals would likely be incentivized to refer the best paying patients to their own facilities. This will reduce the payer mix in other non-hospital affiliated long-term care facilities. Over time, we believe this could make the economics of some non-hospital affiliated facilities unsustainable.

"2. Even more importantly, BLC believes this policy is likely to diminish the quality of care for patients. BLC is a non-profit and committed to caring for all patients at the highest possible standard. However, the only way we can accomplish this is by having a strong payer mix that includes private pay, Medicare and Medicaid patients. If a strong payer mix is no longer possible, quality of care will suffer throughout the entirety of Kentucky's long-term care continuum.

"3. Additionally, BLC agrees with CHFS' contention that long-term care is becoming increasingly specialized. Our facilities are working tirelessly with our local health care partners like St. Elizabeth to ensure patients leaving the hospital receive the best possible care for the condition they have. We believe this continued collaboration of regional health care providers is the best and most efficient way of achieving and sustaining these specialized services that patients need and deserve.

"... we do have significant concerns on the proposed long-term care portion as described above. We hope that CHFS will take these concerns under consideration when completing the required statement of consideration and either remove or significantly revise the proposed changes to long-term care CON process for 'specialized' long-term care facilities."

(b) Response: The Cabinet appreciates the comments regarding specialized long-term care. The Cabinet will amend the proposed State Health Plan to remove language addressing specialized long term care so that the State Health Plan does not include a provision allowing qualified providers to add long term care beds for specialized long term care except for in the specific emergency circumstances outlined in the comment

proposed by Rockcastle Regional Hospital.

(11) Subject: Home Health Care, Revision to Definition

(a) Comment: The Cabinet received three (3) comments regarding the proposed revision in the State Health Plan to define home health agency services in a manner consistent with the statute. The three comments were submitted by representatives of two providers. BrightStar Care submitted comments in support of the revision and Professional Home Health Care Agency submitted comments in opposition. The comments are included and summarized as part of this comment. (This comment relates to "III. Long-Term Care; B. Home Health Agency; Definitions".)

1. Comment: Christian McCutcheon, Owner of BrightStar Care of Louisville, and Chris McCreary, Owner of BrightStar of Northern Kentucky, submitted comments in support of the revision in support of "the change in the definition of 'Home Health Agency' to specify that the provisions of the State Health Plan would apply to Medicare and Medicaid certified agencies". They further stated: "BrightStar Care is a provider of homecare and medical staffing services with over 300 independently owned and operated locations nationwide. BrightStar Care's commitment to the highest standards of quality and safety has been acknowledged by The Joint Commission in its awarding to BrightStar of the prestigious designation of Enterprise Champion for Quality. BrightStar Care nurses, therapists, CNAs, and caregivers deliver professional and compassionate care in the comfort and familiarity of home. In Kentucky, BrightStar Care operates in the Louisville and in the Northern Kentucky metropolitan areas, of note is that these locations are accredited by The Joint Commission…

"These regulatory changes will allow for the provision of healthcare services to a population of consumers who often, under the current regulatory framework, find their healthcare needs unmet. The elimination of these artificial regulatory barriers to healthcare services will allow for more efficient and cost effective delivery of those services."

2. Comment: Darlene Litteral, Health Directions inc., submitted comments on behalf of Professional Home Health Care Agency, Inc. (PHHCA). PHHCA "has provided home health care services for over 40 years. The agency provides the community with skilled nursing services, physical, occupational and speech therapy services, home health aide services, social worker services, infusion services, Home and Community Based Waiver Services, EPSDT services, etc.

In her letter, Ms. Litteral stated: "An update is proposed to change the definition of 'Home Health Agency.' PHHCA objects to the change in this definition and references KRS 13A.222(4)(d) regarding drafting of regulations. Pursuant to the statute, a regulation shall reference definitions contained in a statute by specifically referencing the definition of the statute. In this instance, Home Health Agency is defined in KRS 216.935(2) and as such, the State Health Plan shall reference KRS 216.935 and shall not create a different definition."

3. Comment: Brian W. Lebanion, Secretary, Professional Home Health Care Agency,

Inc., testified at the public hearing and submitted comments. He stated: "Professional Home Health Care Agency, Inc. is a long-standing, non-profit, home health agency providing quality home health services since 1977. Our current service area includes Knox, Laurel, Whitley and Fayette Counties in Kentucky and seven counties in Tennessee." He expressed his organization's support for several of the revisions made to the home health criteria.

"Pursuant to the drafted state health plan update, the definition of 'Home Health Agency' is 'a Medicare or Medicaid-certified agency licensed pursuant to 902 KAR 20:081 to provide intermittent skilled nursing services and other services for restoring, maintaining and promoting health or rehabilitation to patients in their place of residence.' This definition is too narrow in scope to encompass the array of services that home health agency's truly provide.

"This limited view unwittingly opens a door of opportunity for agencies that enter the market under the guise that they only want to provide non-Medicare/Medicaid in home services who do not have to be certified to do so. This premise would preclude them from being subject to the Certificate of Need process. Once established, these agencies could operate part B programs to provide therapy in homes and myriad of other services without having met the necessary requirements to prove that patient rights and safety, quality care and services as well as substantiated cost savings have been secured..."

(b) Response: The revisions to the State Health Plan language addressing home health agencies was intended to reflect the statutory definition of "home health agency" in KRS 216.935(2), which provides:

> "Home health agency" means a public agency or private organization, or a subdivision of such an agency or organization which is licensed as a home health agency by the Cabinet for Health and Family Services and is certified to participate as a home health agency under Title XVIII of the Social Security Act.

Further, the proposed language addresses the requirement that a home health agency be both Medicare certified and licensed by the Cabinet. To remove any question of the Cabinet's compliance with KRS 13A.222(4)(d), the Cabinet will delete the proposed language and instead cite to the statutory definition in KRS 216.935(2).

(12) Subject: Home Health Agencies Established by Qualified Long Term Care Providers

(a) Comment: The Cabinet received six (6) comments regarding the proposed revision in the State Health Plan to expand to licensed nursing facilities Criterion 4, which allows a licensed Kentucky acute care hospital or critical access hospital to establish, notwithstanding the need calculation, a home health agency with a service area no larger than the county in which the facility is located and contiguous counties if the facility documents that in the last twelve (12) months an inability to obtain timely discharge for patients who reside in the county of the facility or contiguous county and who require home health services at the time of discharge. The comments are included and summarized as part of this comment. (This comment relates to "III. Long-Term Care; B. Home Health Agency; Review Criterion 4".)

1. Comment: Dr. Robert H. Long, President and CEO, Baptist Life Communities, submitted comments addressing proposed revisions to the home health review criteria to allow existing long term care facilities experiencing difficulty with discharge of patients to their home to establish their own agency serving those patients: "BLC is the largest provider of housing, healthcare and other services for individuals over 55 in Northern Kentucky. We are also a non-profit faith-based organization and are committed to providing quality healthcare services throughout our region.

"BLC is grateful to the Administration and particularly the Cabinet for Health and Family Services 'CHFS' for including a provision in the proposed revision of the state health plan that provides an appropriate path for addressing the nonsensible limitation on BLC's on Kenton County Home Health Certificate of Need 'CON'. In 1997 BLC's Home Health CON for Kenton County was limited to services provided within our Kenton County facilities. Historically there is no documentation for why this limitation was adopted and is counter-intuitive given that home health services are traditionally provided in a patient's home. For reasons relating to the economics of running a home health program with such a limited scale, we were forced to shutter our home health services earlier this year. It is our hope that this proposed amendment will allow us to reestablish those services to the benefit of the citizens of Kenton County..."

2. Comment: On behalf of LeadingAge Kentucky, a membership organization representing Long Term Care, Senior Living, and providers of services to the Intellectual and Developmentally Disabled, President Timothy L. Veno submitted comments on the State Health Plan. LeadingAge endorses and supports the revision allowing a nursing facility to establish a home health agency to serve residents discharged from the facility to the home. The letter states that many times placement to home when a resident is discharged is stymied because of the lack of a caregiver at home and this proposed revision will provide continuity of care and allow residents to live in the least restrictive environment.

3. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in opposition to the amendment to criterion 4. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated that KHA opposed the modification to criterion 4 to add nursing facilities to the type of facilities authorized to establish a home health agency in circumstances when unable to secure discharge placement. "The purpose of the existing criterion #4 was in recognition that hospitals, which are subject to readmission penalties, needed the ability to provide home health services to prevent readmissions. Also, hospitals indicated having difficulty transferring Medicaid patients to existing home health agencies in several parts of the state. With nearly 500,000 adults under the Medicaid expansion, hospitals needed the ability to provide home health services to meet the needs of these patients when they demonstrated the inability, over the last year, to obtain timely discharge to home health agencies.

"However, the KHA members do not support extending this exception to any

nursing home. We question the need for this as no data has been supplied demonstrating placement difficulty from nursing homes with existing agencies. Also, this exception would appear to permit a nursing home to establish a service that would serve more than their own patients, thus allowing them to bypass the need formula."

4. Comment: Darlene Litteral, Health Directions inc., submitted comments on behalf of Professional Home Health Care Agency, Inc. (PHHCA). She stated: "PHHCA contends that Review Criterion 4 should be removed from the State Health Plan for the same reasons that Criteria 5 was removed. Section 59 of the Kentucky Constitution prohibits these special interest groups from having exceptions not extended to other applicants. Any party that wishes to establish or expand a home health agency should be on equal footing with equal rights, regardless of their current line of business or license type.

"At a minimum, Criterion 4 should be expanded to specify how a facility is required to 'document' inability to obtain timely discharge. Additionally, the number of 'patients' for whom discharge is not timely needs to be identified with details substantiating discharge efforts taken for placement. It should be noted that numerous factors determine if a home health agency can provide services to patients. Licensing laws and regulations restrict home health agencies in the acceptance of patients. Insurance coverage of patients also vary regarding patient eligibility for home health services. If the patient does not qualify for home health services should be discharged to the appropriate level of care for which they are eligible, such as an outpatient facility."

5. Comment: Brian W. Lebanion, Secretary, Professional Home Health Care Agency, Inc., testified at the public hearing and submitted comments. He stated: "Professional Home Health Care Agency, Inc. is a long-standing, non-profit, home health agency providing quality home health services since 1977. Our current service area includes Knox, Laurel, Whitley and Fayette Counties in Kentucky and seven counties in Tennessee." He expressed his organization's support for several of the revisions made to the home health criteria.

"I propose the removal of Section III Long Term Care, B Home Health Agency, Review Criteria Item 4, which states, '4. Notwithstanding criteria 1 and 2, an application by a licensed Kentucky acute care hospital, critical access hospital or nursing facility proposing to establish a home health service with a service area no larger than the county in which the facility is located and contiguous counties shall be consistent with this Plan if the facility documents, in the last twelve (12) months, the inability to obtain timely discharge for patients who reside in the county of the facility or a contiguous county and who require home health services at the time of discharge.'

"The inclusion of this provision does nothing to improve the safety and quality of care and reduce healthcare costs in the Commonwealth. Furthermore, the State Health Plan was never intended to create situations where hospitals or other select facility types monopolize the health care market. Additionally, there is no clear decisive definition of 'timely discharge' or requirement for substantiated documentation of a discharge issue. Not only does this provision lack the necessary elements to gauge its validity, but if there is an issue in a county with discharging to a home health provider then it would be captured in the state's own time tested and proven home health need methodology. When there isn't a need for another provider, there simply isn't a need.

"This provision to allow these entities to establish a home health service in a county in which it is not currently authorized to operate will simply create a silo-referral-based monopoly that includes a new home health entity that is duplicative and unnecessary. Quite frankly, the questionable ability of acute care hospitals, critical care hospitals or nursing facilities, otherwise identified as 'select provider types' to bypass long-standing CON criteria is the epitome of what outsiders view Kentucky as; an incestuous pool of intertwined relationships. This arbitrary act of favoritism runs afoul of the purpose of the regulation and intent of the state health plan. This exception is not fostering the creation an improved system for timely discharge, that already exists, nor will it improve quality metrics and reduce costs. Instead it is a tool to merely be abused by hospital systems and nursing facilities to establish vertical monopolies instead of building true, viable and beneficial interagency/provider relationships."

6. Comment: Michael R. Ewing, Corporate Counsel, Amedisys Home Health, submitted comments through Holly Turner Curry of Cull & Hayden, regarding home health. Amedisys provides care to more than 369,000 patients annually, and operates in 34 states, including Kentucky. "In Kentucky, Amedisys operates 18 home health agencies offering Medicare-certified home health services to residents in 55 counties throughout the state. Throughout Kentucky Amedisys offers traditional home health services for a wide range of diseases and conditions.

"Home health care allows for the delivery of high quality, cost-effective care in the comfort of the patient's home. Home health care offers individualized services that are tailored to the patient's specific medical needs and may supplement or reinforce care from the patient's family and friends. As a result, Kentucky's home health care industry must maintain its economic viability and stability. Amedisys strongly supports Kentucky's Certificate of Need ("CON") Program and the inclusion of review criteria for home health services in the State Health Plan. By maintaining home health review criteria in the State Health Plan, the Cabinet will comply with the statutory purpose of the CON Program and allow for responsible and orderly growth. Moreover, because existing home health agencies, including Amedisys, have the capacity to serve additional patients in their current service areas, it is arguable that a sufficient number of home health agencies exists to meet the needs of current and future patients.

"Amedisys recommends that the exception allowing an acute care hospital, critical access hospital, or nursing facility that is unable to obtain timely discharge for patients to establish its own home health agency be deleted. From a health policy and health planning perspective, this exception is based on multiple faulty assumptions. First, the exception mistakenly presumes that all discharged hospital and nursing facility patients are appropriate for home health services. This is simply not the case. If anything, it has been Amedisys' experience that hospitals and nursing facilities often discharge a patient to home health too quickly. Further, many discharged patients do not have a family member or caregiver to provide 24/7 care to the patient in the home. As a result, the patient is not an appropriate candidate for home health services. This scenario does not equate to a delay in discharges of patients who qualify for home health services, much less indicate that hospitals and nursing facilities need their own home health agencies. Such a relaxation of Kentucky's State Health Plan requirements for home health agencies will not increase access, improve quality, or reduce costs but rather may negatively

impact patients' health, safety, and welfare.

"In other states in which Amedisys operates where CON laws have been repealed or relaxed, the number of home health agencies has dramatically increased. For prime examples one has to look no further than Texas, Florida, Illinois, and South Carolina. These states clearly illustrate the consequences of eliminating or relaxing CON oversight in home health. Historically, when CON regulation is relaxed or lifted, states quickly experience dramatic growth in the number of home health agencies, which may lead to CMS and OIG fraud investigations. Because of fraud cases in other states, CMS implemented a moratorium on new providers and has extended the moratorium several times, most recently on January 30, 2018. The experience in these states also shows that elimination or relaxation of CON results in over capacity, which causes staffing shortages of health care professionals. This staffing shortage, in and of itself, lowers quality and fragments health care delivery networks. These are undesirable results in Kentucky.

"In contrast, Amedisys supports the deletion of the exemption for existing Kentucky home health agencies that met or exceeded certain quality measures. There are multiple reasons that support removal of this review criterion from the Home Health Agency Review Criteria. Going through the CON process provides publicity to the market about those who would enter its provider space, helps to separate those whose additional services are needed and those who are not, and fosters awareness — even for existing agencies — of the support available to an increased presence in the area. The Cabinet's deletion of the exemption review criterion recognizes all of these important facts, among others. Therefore, the proposed amendment should remain intact.

"For the reasons stated above, Amedisys supports the Cabinet's retention of review criteria in the State Health Plan for home health services and deletion of the exemption for existing Kentucky home health agencies that met or exceeded certain quality measures contained in Review Criterion 5 of the State Health Plan. Amedisys also advocates for the deletion of Review Criterion 4."

(b) Response: The Cabinet appreciate the comments. After thoughtful consideration of the comments, the Cabinet will make further revisions to Review Criteria 4 to limit it to home health agencies serving only patients discharged from the applicant facility.

(13) Subject: Home Health Agencies Expanding Service Area if They Meet Medicare Home Health Compare Standards

(a) Comment: The Cabinet received two (2) comments in support of the proposed revision deleting review criterion 5 from the State Health Plan review criteria for home health agencies. The comments are included and summarized as part of this comment. (This comment relates to "III. Long-Term Care; B. Home Health Agency; Review Criterion 5".)

1. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments in support of the deletion of criterion 5. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated: "KHA agrees with the Cabinet's strike of criterion 5, which allows an existing home health agency to expand to one or more counties contiguous to its home county."

2. Comment: Darlene Litteral, Health Directions inc., submitted comments on behalf of Professional Home Health Care Agency, Inc. (PHHCA). She stated: "PHHCA applauds the update to remove Review Criteria 5 which carved out a certain group of entities and provided them with the ability to back-door their way into licensing as a home health agency. This Review Criteria completely ignored the long-standing requirement of need for services and disregards the state's own calculation of need for home health agencies."

(b) Response: The Cabinet appreciates the comments and Review Criterion 5 will remain deleted from the State Health Plan.

(14) Subject: Implementation of HB 444 for In Home Care

(a) Comment: The Cabinet received a comment regarding home health agencies and the Cabinet's implementation of House Bill 444, which included legislation removing mobile health services and rehabilitation agencies, among other provider types, from the OIG licensing requirement.

Brian W. Lebanion, Secretary, Professional Home Health Care Agency, Inc., testified at the public hearing and submitted comments. He stated: "Professional Home Health Care Agency, Inc. is a long-standing, non-profit, home health agency providing quality home health services since 1977. Our current service area includes Knox, Laurel, Whitley and Fayette Counties in Kentucky and seven counties in Tennessee." He expressed his organization's support for several of the revisions made to the home health criteria.

"It is imperative that the Cabinet include the necessary framework to plan for and manage the unnecessary expansion of services allowed by House Bill 444. A specific example is the recent opinion letter issued to allow an outpatient therapy clinic to expand their services to provide in-home therapy without a certificate of need. The current definition of home health agency, which is lacking, does include the words 'in their [the patient's] place of residence.' This alone indicates that any skilled service such as therapy being provided in the patient's place of residence should fall appropriately under the purview of home health. House Bill 444 was not meant to circumvent the purpose of the State Health Plan and create loopholes for various provider types to masquerade as a home health agency. To coin a phrase, 'if it walks like a duck, and talks like a duck, it's a duck!' If health services that are normally and justifiably provided by a home health agency are being provided by another type of entity in the patient's place of residence, then it's home health services and should be treated as such.

"The Cabinet needs to clearly control expansion of these unnecessary and duplicative services for many reasons. The Cabinet does not have a tracking mechanism in place to monitor the level of care needs for these services nor do they track utilization. Allowing entities to provide therapy or other services such as infusion therapy in the home environment without established methods to assure quality, safety, utilization and need will only increase cost to the Commonwealth, risk to the patients and damage Kentucky's fragile healthcare structure.

"In fact, one look at the latest published home health need calculations tells you that there simply isn't a need for increased in home health providers of any kind nor does it support increased leniency of the CON process to allow non-licensed, non-vetted, provider types to render care in the home environment. The latest statistics published from July 2017 shows that only 7 counties in the state meet the need threshold to establish a new home health agency, a mere 5.8% of all counties. Home Health agencies are already meeting the needs of people who require physical, occupational and speech therapy, infusion therapy, and other skilled services in the home. And, they are doing it under the appropriate conditions of participation that establish what is needed in order to provide quality, safe, fiscally sound and effective care. Allowing other provider types to render care in the home omits this vitally important oversight. House Bill 444's statement of consideration clearly allows the Office of Inspector General to include what is necessary in the State Health Plan to appropriately govern the changes that are being implemented by the legislation. The current State Health Plan draft does not contain the necessary elements to control the unnecessary expansion of these services and the state's planning processes and statistics do not support expansion of these services as there is NO NEED. We propose a new section be added to V. Miscellaneous Services that will assure adequate controls are in place to sufficiently manage them."

(b) Response: The Cabinet appreciates this comment. The Cabinet is currently in the process of implementing changes precipitated by HB 444 and changes necessary to ensure access to quality care and removing unnecessary burdens on providers. The State Health Plan will not be amended at this time in response to this comment.

(15) Subject: Intermediate Care Facilities for Individuals with an Intellectual Disability

(a) Comment: A comment regarding the changes in the State Health Plan regarding Intermediate Care Facilities for Individuals with an Intellectual Disability was received from Protection & Advocacy. (This comment relates to "III. Long-Term Care; E. Intermediate Care Facility for Individuals with an Intellectual Disability; Review Criteria".)

Heidi Schissler Lanham, Legal Director, Protection and Advocacy, commented regarding the criteria for intermediate care facilities for individuals with an intellectual disability. She stated: "The criteria should be changed to prohibit the transfer of public ICF/MR beds to private entities potentially in violation of the Cabinet's agreement in *Michelle P. v. Birdwhistell, et al,* U.S. District Court, Commonwealth of Kentucky, Frankfort Division, Civil Action #02-23-JMH.

"The new language should read:

> No application for a new ICF-MR/DD shall be consistent with this Plan unless it is limited to a transfer of ICF-MR/DD beds from an existing <u>private</u> ICF-MR/DD facility to the proposed <u>private</u> ICF-MR/DD facility. No application to increase the number of beds at an existing <u>private</u> ICF-MR/DD facility shall be consistent with the Plan unless the increase in beds is accomplished by transferring beds from an existing <u>private</u> ICF-MR/DD facility.

(b) Response: The Cabinet has considered this comment and will not amend the ICF/IID review criteria at this time. The existing review criteria provides the Cabinet with flexibility

necessary to transfer public ICF/IID beds to private ICF/IID facilities without increasing the total number of ICF/IID beds available statewide.

(16) Subject: Cardiac Catheterization, Clarification of Applicability to Kentucky Hospitals

(a) Comment: The Cabinet received one comment requesting clarification in the cardiac catheterization review criteria that qualified acute care hospitals must be located in Kentucky. The comment is included and summarized as part of this comment. (This comment relates to "IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criterion 4".)

Michael T. Rust, President, Kentucky Hospital Association, submitted comments requesting clarification in the cardiac catheterization review criteria that qualified acute care hospitals must be located in Kentucky. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

"In addition, KHA requests a clarifying change to criterion #4a. This criterion contains the requirements for expansion of a hospital's existing diagnostic cardiac catheterization program to a therapeutic program. Specifically, criterion #4a states that the applicant shall be an existing licensed acute care hospital. KHA member hospitals believe this criterion is intended to be interpreted as requiring that the applicant be a Kentucky licensed hospital only. This understanding is supported by criterion 4b which requires the applicant to have performed a minimum volume of diagnostic studies as reported to the Cabinet in administrative claims data, which would only include Kentucky hospitals. Therefore, KHA would appreciate the Cabinet amending criteria #4a to clarify that the applicant shall be an existing licensed 'Kentucky' acute care hospital."

(b) Response: The Cabinet appreciates the comment and will incorporate the suggested revision in the final version of the State Health Plan.

(17) Subject: Cardiac Catheterization, Establishment of Comprehensive Program

(a) Comment: The Cabinet received two (2) comments in support of the new criteria to allow qualified hospitals without existing cardiac catheterization services to establish a comprehensive (diagnostic and therapeutic) program. The Cabinet received one comment suggesting revisions to limit the proposed review criteria. The comments are included and summarized as part of this comment. (This comment relates to "IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criterion 7".)

1. Comment: State Senator Dr. Ralph Alvarado, submitted comments in support of the State Health Plan revision previously proposed by Lifepoint Hospitals concerning the establishment of a comprehensive diagnostic and therapeutic cardiac catheterization service at the Clark Regional Medical Center (CRMC). Dr. Alvarado notes that "There are currently no therapeutic catheter programs within the 120 miles between Prestonsburg and Lexington. Readily available therapeutic catheter services and

reduction travel time for heart attack patients, who are traveling toward Lexington from the Mountain Parkway or interstate 64, will significantly reduce the factor of morbidity rates. Because Clark County is contiguous to Fayette County, the prior State Health Plan criteria have precluded CRMC from establish a diagnostic catheter service. Since CRMC does not have a diagnostic catheter service, it also cannot establish a therapeutic catheter service. Clark Regional Medical Center is affiliated with the cardiology program at the University of Kentucky Medical Center, and is staffed with UK cardiologists. This relationship with the University of Kentucky and its cardiologists will ensure that the program at CRMC will have the highest quality of services for its patients. I ask your department to look upon this application favorably."

2. Comment: Barbara Kinder, Interim CEO, Clark Regional Medical Center, submitted comments in support of the addition of Cardiac Catheterization Services Review Criterion 7 concerning comprehensive (diagnostic and therapeutic) cardiac catheterization services. Ms. Kinder stated that CRMC's support is based upon the information previously submitted by Robert Parker, Chief Executive Officer, Clark Regional Medical Center, by letter dated June 7, 2018. A copy of that letter was attached to her comments.

3. Comment: Michael T. Rust, President, Kentucky Hospital Association, submitted comments recommending a change to the new language in Criterion 7. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated: "The proposed plan contains a new criterion #7 which would allow a comprehensive (diagnostic and therapeutic) cardiac catheterization service to be established outside of the need criteria if certain conditions are met. Those include being a licensed Kentucky hospital affiliated with the cardiology program of the primary teaching facility of an academic medical center and located within 50 miles of the teaching facility and in a county that does not have cardiac catheterization services. The KHA member hospitals do not support this criteria in its current form as it is overly broad and raises many questions. For example, there is no definition of a 'primary teaching facility of an academic medical center' which could include as many as three such facilities outside of the Commonwealth of Kentucky. The definition of applicant facility could include both acute care hospitals and critical access hospitals without regard to any other criteria except the lack of services in the county and their drive time to an academic medical center. Finally, the criteria does not address requirements for an affiliation agreement similar to the prior cardiac catheterization pilot program.

"Several rural hospitals presented alternative language to address these issues and narrow the scope of this exception. This alternative would assist a limited number of acute care rural hospitals which have a relationship with one of the Kentucky University hospitals obtain the ability to establish this service in recognition of the rural population they serve and to reduce travel times for heart attack patients to get treatment. It addresses KHA's concerns by:

- Limiting the academic medical center to University of Kentucky or University of Louisville;

- Defining the affiliation as a written agreement in place for at least two years with specific focus on improving cardiology care in the applicant hospital's county or service area;
- Limiting the applicant to acute care (non-critical access) Kentucky hospitals that are not only within 50 miles from their affiliated teaching hospital but are located in a county with at least 30,000 population that lacks cardiac catheterization services and where the applicant has at least 20,000 ED visits annually. These metrics are similar to the original cardiac catheterization rural pilot hospital.

"This alternative proposal was reviewed by KHA's CON Committee and is supported by a majority of its members. Therefore, KHA recommends that it replace the language in criterion 7 as follows:

> Notwithstanding criteria 1,2,3,4,5 and 6, an application to establish a comprehensive (diagnostic and therapeutic) cardiac catheterization service shall be consistent with this Plan if:
>
> a. The applicant is a licensed Kentucky acute care (non-critical access) hospital affiliated with the cardiology program of the primary teaching facility of the University of Kentucky or the University of Louisville (collectively "Kentucky academic medical center") through a formal affiliation in the form of an agreement or a contract in place for at least two years and specifically focusing on improving Cardiology care in the service area or county of the applicant hospital[~~an academic medical center~~];
> b. The medical director and the cardiologists staffing the applicant's proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of an academic medical center;
> c. The applicant hospital is located within fifty (50) highway miles of the primary teaching facility of an a Kentucky academic medical center; and
> d. The applicant hospital is located in a county that does not have an existing cardiac catheterization service and has a population greater than 30,000; and
> e. The applicant hospital has a minimum of 20,000 emergency department encounters on an annualized basis.

(b) Response: The Cabinet appreciates the comments and will incorporate the agreed upon revisions into the State Health Plan, with slight modifications.

(18) Subject: Cardiac Catheterization, Conversion of Mobile Labs to Fixed Site

(a) Comment: The Cabinet received a comment requesting a revision to the State Health Plan to allow for the conversion of mobile cardiac catheterization labs to fixed site locations. (This comment relates to "IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criteria".)

Hollie Harris Phillips, Vice President of Corporate Strategy for Appalachian Regional Healthcare (ARH), submitted comments in support of the certificate of need program and

described it as providing access to quality health services across Kentucky. ARH is the largest integrated health system in Eastern Kentucky with a sixty year history of serving its communities. ARH is committed to enhancing cardiac care in Eastern Kentucky and currently operates two comprehensive cardiac catheterization labs and an open heart surgery program in Hazard. ARH is the only provider still operating a mobile cardiac catheterization lab in Kentucky. The mobile service provides access so that patients do not have to travel great distances to receive cardiac care. However, receiving care in a mobile setting is not ideal for cardiac patients, and the Cabinet has discouraged the use of mobile cath labs by not allowing any mobile approvals in the previous state health plan and the current state health plan does not allow approval. ARH requests approval to convert the mobile to fixed site, which will allow ARH to provide better physical conditions for patients and increase access. Specifically, ARH proposes the following language be added as a new Criterion 9:

> 9. Notwithstanding the above criteria, an application to establish a fixed-site diagnostic cardiac catheterization service shall be consistent with this State Health Plan if the following criteria are met:
>
> (a) The applicant is an acute care hospital that is providing diagnostic cardiac catheterization with intermittent equipment through a mobile license; and
>
> (b) The applicant is proposing to replace the mobile service at its hospital with a fixed-site, diagnostic cardiac catheterization service.

(b) Response: The Cabinet appreciates the comment and suggested revision. Quality indicators strongly favor fixed site services over mobile sites and this revision is reasonable in light of the need to improve access to quality services.

(19) Subject: Magnetic Resonance Imaging

(a) Comment: The Cabinet received a comment opposing the proposed revisions to Magnetic Resonance Imaging review criterion. (This comment relates to "IV. Diagnostic and Therapeutic Equipment and Procedures; B. Magnetic Resonance Imaging; Review Criteria".)

Michael T. Rust, President, Kentucky Hospital Association, submitted comments in opposition to the proposed revisions to Magnetic Resonance Imaging review criterion. On behalf of the Association's 127 member hospitals, Mr. Rust stated that his submitted comments reflect areas of strong consensus by the Association, which has the goal of streamlining the certificate of need program to reflect the growth in technology and to reduce regulatory barriers where possible.

He stated: "MRI continues to be a costly diagnostic modality, including equipment acquisition, state-of-the art upgrades to hardware and software, contrast agents, and the subsequent cost to the patient for use of the service. KHA recommends that the criteria outlining the demonstration of specific need for MRI services should be retained and is opposed to the removal these criteria. A credible demonstration of need for additional MRI services throughout the Commonwealth has and would continue to discourage proliferation of unnecessary MRI services, a definition of purpose found in the Cabinet's current Certificate of Need website:

Who We Are

The Kentucky certificate of need process prevents the proliferation of health care facilities, health services and major medical equipment that increase the cost of quality health care in the commonwealth.

"The recent low historic numbers of applications for MRI service may well point to success of this purpose. Utilization Statistics from CY2017. KHA examined utilization statistics for member facilities during the calendar year 2017. Excluding all out-of-state residents served, there were patients who obtained MRI services as part of their case from all 120 counties in the Commonwealth. Those cases were served by KHA member-related MRI providers located in 75 Kentucky Counties, which are well-distributed across the Commonwealth. Each Area Development District has a minimum of at least two counties where MRI service is available.

"As an example, residents of Hickman County had a total of 189 cases where one or more MRI procedures were performed. These were distributed among seven (7) providers, three of which were located in the Purchase Area Development Districts (179 cases or 94.7% of these cases). It would appear from these statistics that Need Criteria for MRI services have adequately served the people of the Commonwealth.

"These same utilization statistics showed nearly six of ten cases were covered by governmental payers (Medicare and Medicaid). Cases from five (5) Area Development Districts were between 56% and 58%. Cases from eight (8) Area Development Districts were between 60% and 69%. Cases from two (2) Area Development Districts were in excess of 70%.

"In addition to supporting the retention of the current need criteria contained in the Plan, KHA supports the addition of criteria requiring the applicant's proposed service consistent with the American College of Radiology Accreditation requirements, with the service be accredited within twelve (12) months of licensure. We thank the Cabinet for including a method to include quality measures in this need criteria."

(b) Response: The Cabinet appreciates the comment. Upon further review of Kentucky certificate of need laws and the emergence of MRI as a first line diagnostic tool to which access should not be hindered, the Cabinet has deleted MRI from the State Health Plan.

(20) Subject: Positron Emission Tomography Equipment

(a) Comment: A comment requesting changes in the State Health Plan Review Criteria for PET was submitted. The comment is included and summarized as part of this comment. (This comment relates to "IV. Diagnostic and Therapeutic Equipment and Procedures; C. Positron Emission Tomography Equipment; Review Criteria".)

Karen Stevens, Director of Sales, Shared Medical Services, Inc., submitted the following comments: "Shared Medical Services has been a leader in providing diagnostic imaging to health care facilities since 1980. We are one of the largest providers of mobile PET-CT imaging in the United States. With respect to the current State Health Plan review criteria for PET services..., we propose that existing Criteria 1., 2., and 4. be deleted. We propose that existing Criterion 3. remain and become Criterion 1. Specifically, we propose the PET services review criteria be revised as follows:

1. The application shall document a projection of need for the PET unit that shall include demographic patterns, including analysis of applicable

population-based health status factors, estimated utilization by patient clinical diagnoses category (ICD-10), and documentation demonstrating that the applicant is providing or has referral arrangements with other medical providers that offer comprehensive cancer and cardiac diagnostic and treatment services.

"In the alternative, we propose that the current PET services review criteria remain and that the following criterion be added after the existing Criterion 4:

5. Notwithstanding all of the foregoing criteria, an application submitted to establish or expand a mobile PET service shall be consistent with this plan if the applicant has arrangements to provide services to a licensed acute care hospital or critical access hospital in the Planning Area and has the support of that hospital.

"There are some rural areas in Kentucky in which the utilization requirements found in the current State Health Plan PET services review criteria cannot be met; however, there is a need for another PET provider. If there is only one PET provider in a Planning Area, for example, and that provider has outdated equipment, charges to much for its services, or does not provide timely and quality services, there is no other option for the hospitals and other providers who have patients requiring a PET scan. Revising the PET services criteria would allow for additional PET services providers and would give patients and other medical providers a choice. Revising the criteria would lead to more efficiencies through limited competition."

(b) Response: The Cabinet appreciates the comment and has added, with modifications, the suggested review criterion 5 to the State Health Plan Review Criteria for PET as a recognition of alternative business models and contracting to achieve the overall goal of access to care.

(21) Subject: Ambulance Services

(a) Comment: The Cabinet received a comment regarding the review criteria for ambulance services. The comment is included and summarized as part of this comment. (This comment relates to "V. Miscellaneous Services; A. Ambulance Service; Review Criteria".)

Charles R. "Chuck" O'Neal, Deputy Executive Director of Kentucky Board of Emergency Medical Services, submitted comments suggesting changes to the review criteria addressing ambulance services necessary for the State Health Plan review criteria to be consistent with recent updates to the classifications for transport services. The suggested changes include incorporation of the geographic specification requirement set forth in ambulance licensing regulation 202 KAR 7:501 and deletion of criterion 3.

(b) Response: The Cabinet appreciates the comment from the Kentucky Board of Emergency Medical Services and has revised the ambulance review criteria to be consistent with recent regulatory changes impacting licensure for ambulances. Under the "Definition", the defined term will be changed from "Ambulance Service" to "Ground ambulance services." The definition will read as follows:

"Ground ambulance services" means services provided by a Class I, II, III, or

IV ground ambulance transport agency. The license classifications are established in KRS 311A.030 and 202 KAR 7:545.

This revision clarifies the classifications included as a component of the State Health Plan. For classifications not addressed, certificate of need applications will be subject to nonsubstantive review per 900 KAR 6:075, Section 2(3)(a).

Additionally, the Review Criteria has been changed. Specifically Criterion 1 has been revised to require the applicant to "document that all agencies licensed to provide ambulance service or medical first response within the applicant's proposed geographic service area have been given notice of the applicant's intent to obtain a certificate of need. The notice shall describe the scope of service and proposed geographic service area with specificity; and".

Also, Criterion 3, which was limited to Class II or III applications, has been deleted.

(22) Subject: Private Duty Nursing

(a) Comment: The Cabinet received six (6) comments regarding the deletion of review criteria for private duty nursing from the State Health Plan. The comments are included and summarized as part of this comment. (This comment relates to "V. Miscellaneous Services").

1. Comment: Christian McCutcheon, Owner of BrightStar Care of Louisville, and Chris McCreary, Owner of BrightStar of Northern Kentucky, submitted comments in support of the proposed revision to remove the private duty nursing language from the State Health Plan. They stated: "BrightStar Care is a provider of homecare and medical staffing services with over 300 independently owned and operated locations nationwide. BrightStar Care's commitment to the highest standards of quality and safety has been acknowledged by The Joint Commission in its awarding to BrightStar of the prestigious designation of Enterprise Champion for Quality. BrightStar Care nurses, therapists, CNAs, and caregivers deliver professional and compassionate care in the comfort and familiarity of home. In Kentucky, BrightStar Care operates in the Louisville and in the Northern Kentucky metropolitan areas, of note is that these locations are accredited by The Joint Commission.

"These regulatory changes will allow for the provision of healthcare services to a population of consumers who often, under the current regulatory framework, find their healthcare needs unmet. The elimination of these artificial regulatory barriers to healthcare services will allow for more efficient and cost effective delivery of those services."

2. Comment: Colleen McKinley, Attorney, submitted a comment on behalf of Interim Healthcare of Northern Kentucky to endorse the proposed removal of private duty nursing from the State Health Plan, which will result in such applications receiving nonsubstantive review status.

3. Comment: On behalf of LeadingAge Kentucky, a membership organization representing Long Term Care, Senior Living, and providers of services to the Intellectual and Developmentally Disabled, President Timothy L. Veno submitted the following

comments: "LeadingAge strongly endorses and supports the elimination of the need criteria for private duty nursing. Our members seeking to provide nursing care to their residents not housed in a health care facility have been forced to seek a home health agency license. The home health agency licensure process has proven to be far too onerous of a process when in reality our members are only serving a few patients. This is a common sense approach that does not involve a capital outlay and will enable us to provide care in the least restrict setting."

4. Comment: Darlene Litteral, Health Directions inc., submitted comments on behalf of Professional Home Health Care Agency, Inc. (PHHCA). She stated: "The proposed update to the State Health Plan proposes to remove Private Duty Nursing (PDN) in its entirety. PDN has been included in the State Health Plan for many years with the purpose of preventing 'the proliferation of health care facilities, health services and major medical equipment which increases the cost of quality health care within the Commonwealth', as required by KRS 216B.010. One of the major impacts of this proposed change would be a shift in the burden of proof from the applicant requesting PDN to the affected party opposing the application. By shifting the burden of proof, this eases the certificate of need process for the applicant; therefore, allowing the proliferation of PDN services in the Commonwealth...

"The regulatory impact analysis for this change stated that there would be no impact to any state agency/department regarding cost to the administrative agency and the response was 'initially, none.' This statement is incorrect. When PDN providers proliferate due to the change in burden of proof, costs will increase for the licensing agencies, inspection agencies, and Medicaid expenditures will increase."

5. Comment: Brian W. Lebanion, Secretary, Professional Home Health Care Agency, Inc., testified at the public hearing and submitted comments. He stated: "I also propose the re-inclusion of Section V. Miscellaneous Services, D. Private Duty Nursing. There simply is no support or evidence to remove the provision related to private duty nursing services. This change weakens the efficacy of the certificate of need process by allowing the proliferation of unnecessary and costly private duty providers. There is no valid data cited that indicates the removal of this section is warranted.

"Due to my numerous years of experience in the industry and my personal knowledge that there is no need for additional private duty nursing service providers, I believe that the current language contained in the state health plan protects the Commonwealth against duplicative, unnecessary and proliferate services. It is cost prohibitive to remove the private duty section from the State Health Plan, especially in light that we already have a strained healthcare system."

6. Cameron Cook, Area Director, Brightmore Home Care of Kentucky, LLC, submitted comments through Holly Turner Curry of Cull & Hayden, regarding the removal of the private duty nursing provisions. The letter stated: "Brightmore is a full-service private duty nursing agency licensed to serve Ballard, Bath, Calloway, Carlisle, Fulton, Graves, Hickman, Marshall, McCracken, Menifee, and Rowan Counties. While Brightmore is a full-service private duty nursing agency with an unrestricted license, it focuses on primarily serving beneficiaries qualified to receive health benefits under the Energy

Employees Occupational Illness Compensation Program Act ('EEOICPA')...

"The private duty nursing industry in Kentucky must maintain its economic viability and stability. Brightmore strongly supports the Certificate of Need Program and the inclusion of private duty nursing review criteria in the State Health Plan for responsible and orderly growth. Maintaining review criteria in the State Health Plan for private duty nursing services directly complies with the purpose of Kentucky's Certificate of Need laws by keeping applications seeking to establish or expand private duty nursing services under full, formal review." The letter then restated KRS 216B.010, which establishes the findings and purposes of the CON law and summarized the formal review process for CON applications.

"...Requiring evidence of a provider's ability to provide private duty nursing services in a cost-efficient and quality manner ensures the health, safety, and welfare of Kentucky citizens.

"The proposed deletion of the Private Duty Nursing Review Criteria changes review of applications to the expedited, non-substantive review process. Under non-substantive review, need for the proposal is presumed. The affected party, not the applicant, has the burden of proof to rebut the presumed need for the proposal by a preponderance of the evidence. If the proposed deletion stands the applicant will no longer be required to prove that the application is consistent with: (1) Consistency with the State Health Plan; (3) Interrelationships and Linkages; (4) Costs, Economic Feasibility, and Resources Availability; and (5) Quality. Without evidence of an applicant's ability to provide services in a quality manner, the health, safety, and welfare of Kentucky citizens could be compromised. Further, it may result in providers unexpectedly exiting the market due to financial constraints, which could limit access to private duty nursing services and potentially impact the ability of existing providers to continue to operate.

"Maintaining the State Health Plan Private Duty Nursing Review Criteria will positively impact private duty nursing providers and the individuals they serve. When an application is processed under full, formal review, the applicant is required to show that it has appropriate interrelationships and linkages to implement its proposal, it is a financially viable provider that can deliver services in a cost-effective manner, and it is a quality provider. It is critical to the life, safety, and welfare of Kentucky citizens that applicants must demonstrate their consistency with these statutory and regulatory requirements, particularly out-of-state applicants that have not previously served Kentucky citizens and are not regulated under the licensure standards established by the Cabinet's Office of Inspector General. By retaining the requirements for out-of-state providers, it could prohibit a proliferation of unnecessary private duty nursing services that are not financially viable, and cannot be financially viable in Kentucky, because they do not have appropriate referral sources to implement their proposal. Further, by having to demonstrate compliance with quality requirements, it may keep certain out-of-state providers with negative licensure and regulatory history out of the Kentucky market.

"If the State Health Plan is amended to increase the number of private duty nursing agencies without an understanding as to how to address unmet needs, the viability of Kentucky's existing agencies could be compromised as the patient base would be eroded by an influx of additional providers. Kentucky has maintained a stable and economically viable private duty nursing industry that delivers quality care to an increasing number of patients. Unlike other states where there has been a proliferation of private duty nursing

services and agencies, Kentucky has not experienced the same level of federal and state investigations of fraud and abuse.

"Kentucky's Certificate of Need Program also balances the staffing needs of existing providers with the approval of new providers. The retention of the State Health Plan Private Duty Nursing Review Criteria deters the proliferation of unnecessary private duty nursing providers that are staffed by potentially recruiting personnel away from existing providers. In turn, this allows existing providers to continue the level services they offer and remain in the market.

"By maintaining the Private Duty Nursing Review Criteria in the State Health Plan, the rigorous standards by which new and additional private duty nursing agencies are reviewed will remain virtually unchanged. Not only may retention of the review criteria positively impact existing providers, it may also affect the health, safety, and welfare of Kentucky citizens for the better. Brightmore advocates for the inclusion of the Private Duty Nursing Review Criteria in the State Health Plan."

(b) Response: The Cabinet appreciates the comments and private duty nursing will remain deleted from the State Health Plan. Many in home nursing services are not intermittent and not included in the Medicare home health benefit but rather are services necessary for chronically ill patients to live in the home or specialized services limited to specific condition. By deleting private duty nursing from the State Health Plan, a certificate of need application proposing private duty nursing services will be subject to nonsubstantive review and a barrier to care will be eliminated.

(23) Subject: Cabinet-Requested Changes

(a) Comment: During their review and edits of the State Health Plan, Molly Lewis and Donna Little, Cabinet for Health and Family Services, identified additional changes that were needed throughout the State Health Plan to comply with the drafting and formatting requirements of KRS Chapter 13A.

Additionally, a change was requested for the Review Criteria for Psychiatric Services for Children and Adolescents. Current Review Criteria 4.b. requires an application for new psychiatric beds for children and adolescents to include "an inventory of current services in the ADD". That requirement does not clarify what is meant by "current services", which could be broadly interpreted to mean all services within the ADD, not just those limited to children or adolescent psychiatric beds.

For the Acute Care Hospital criterion 2.e., clarification was requested as to whether the "or" in the second paragraph should be "and", given the meanings of those conjunctions under KRS 13A.220(2)(c).

For the Nursing Facility Beds definition, second paragraph, clarification was requested regarding the reference to "provisions of this Plan" for continuing care retirement communities, as those communities are not CON-approved and are not addressed elsewhere in the State Health Plan.

(b) Response: The Cabinet has made the requested changes, which included correcting a Web site address, changing "recent" to "recently" in the phrase "most recent published"; changing "which" to "that"; changing "its" to "the applicant's"; correcting a cross-reference;

changing "applications" to "an application" and other singular-plural changes; changing "outlined" to "established"; dividing a compound sentence into two sentences for clarity; defining an acronym, and adjusting punctuation. Additionally, the Table of Contents was amended to update page numbers and align titles.

Additionally, the Psychiatric Services for Children and Adolescents Review Criteria was amended to require the application for new psychiatric beds to include "an inventory of all facilities with children or adolescent psychiatric beds in the ADD and the number of beds", rather than "an inventory of current services in the ADD".

For the Acute Care Hospital criterion 2.e., "or" was changed to "and" to require an applicant to have "identified and would retain trained, experienced, and licensed personnel".

For the Nursing Facility Beds definition, second paragraph, the provisions was changed from "nursing home beds established under the continuing care retirement community (CCRC) provisions of this Plan" to "nursing home beds established as part of a continuing care retirement community (CCRC)".

V. Summary of Statement of Consideration and Action Taken by Promulgating Administrative Body

The public hearing on this administrative regulation was held, and written comments were received. The Cabinet for Health and Family Services, Office of Inspector General, Division of Certificate of Need has responded to the comments and will be amending the administrative regulation and material incorporated by reference as follows:

Page 1
Section 2(1)
Line 19
After "October", insert "15,".

Changes to the Material Incorporated by Reference

(Please note that the page numbers relate to the "clean" copy of the State Health Plan filed with the ordinary administrative regulation on July 13, 2018, with an edition date of "October 2018". The State Health Plan filed with this Amended After Comments version has an edition date of "October 15, 2018".)

Page i, Edition Date, Top Right Corner
After "October", insert "15,".

Page i, Edition Date, Middle of Page
After "October", insert "15,".

Page ii, Table of Contents
- Page Numbers were adjusted to reflect the final page numbers in the October 15, 2018 clean document.

Page ii, Table of Contents, III. Long-Term Care, E. Intermediate Care Facility for

Individuals with Intellectual Disability
After "INDIVIDUALS WITH", insert "AN".

Page ii, Table of Contents, IV. Diagnostic and Therapeutic Equipment and Procedures

- For Item B., after "B.", delete "MAGNETIC RESONANCE IMAGING 45"
- For Item C., delete the notation "C.".
- Renumber subsequent items D. and E. as C. and D., respectively.
- After "NEW TECHNOLOGY", delete "PROGRAM".

Page iii, Technical Notes, Item 2.
After "Web site:", insert "https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx".
Delete "http://chfs.ky.gov/oig/cn".

Page 3, I. Acute Care; A. Acute Care Hospital; Review Criterion 2.e.
After "experienced,", insert "and".
Delete "or".

Page 6, I. Acute Care; B. Acute Care Beds; Review Criterion 2.b.
After "bed units;", insert "and".

Page 6, I. Acute Care; B. Acute Care Beds; Review Criteria 3.b. and 4.
After "timeframe", delete "; and" and delete Review Criterion 4, except the final period.
The combined deletion includes:

; and

4. Notwithstanding criteria 1, 2, and 3, an application by an existing licensed acute care hospital shall be consistent with this Plan if the licensed acute care hospital:

a. Is verified as a Level I or Level II Trauma Center; and

b. Has received written acknowledgement from the Cabinet for Health and Family Services, Office of Inspector General, Division of Certificate of Need recognizing that an emergency exists with respect to acute care beds being applied for

Page 7, 1. Acute Care; C. Comprehensive Physical Rehabilitation Beds; Review Criteria
In Criterion 1., after "from the most", insert "recently".
Delete "recent".
In Criterion 2., after "from the most", insert "recently".
Delete "recent".

Page 10, I. Acute Care; D. Special Care Neonatal Beds; Definition
After "as Level II,", delete "Advanced Level II,".
(This changes the listing of categories of Special Care Neonatal Beds.)

Page 10, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria, paragraph 1
After "for Level II,", delete "Advanced Level II,".
(This changes the listing of applications for Special Care Neonatal Beds.)

Page 10, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria, paragraph 2

After "for Level II", delete ", Advanced Level II,".

(This changes the listing of applications for Special Care Neonatal Beds.)

After "in the most", insert "recently".

Delete "recent".

Page 11, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds, Review Criterion 5

After "with the most", insert "recently".

Delete "recent".

Page 11, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds, Review Criterion 7

In the first line, after "an applicant for", delete "Advanced".

In the second line, after "will provide", insert "advanced".

This revises the wording of advanced care to clarify that "Advanced Level II" is not intended to create a new provider type. This review criterion will read as follows:

> 7. Notwithstanding criterion 5, an applicant for [~~Advanced~~] Level II special care neonatal beds that will provide advanced care for stable or moderately ill newborn infants who are born at ≥ twenty-eight (28) weeks gestation, or who weigh ≥ 1200 grams at birth, or require ventilation for > twenty-four (24) hours shall: ...

Page 12, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds, Review Criterion 7.a.v.

After "for patients", insert "that".

Delete "which".

Page 13, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds, Criterion 9

After "9.", insert the following:

> Notwithstanding criteria 1 and 3, if the most recently published inventory and utilization data indicates that the applicant had 700 or more annual births and that the average occupancy of the applicant's existing Level II special care neonatal beds over twelve (12) months was eighty (80) percent or greater, an application to establish up to eight (8) additional Level II special care neonatal beds shall be consistent with this Plan;
>
> 10.

In the criteria that will now be numbered as 10., but was 9., after "a Level II program", insert "through conversion".

Page 13, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level II special care neonatal beds, Criterion 10

Before "10. Notwithstanding criterion 7,", insert "11.".

Delete "10.".

Page 15, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level III special care neonatal beds, Criterion 2

After "shall document", insert "the applicant's".

Delete "its".

Page 17, I. Acute Care; D. Special Care Neonatal Beds; Review Criteria for Level III special care neonatal beds, Criterion 3

After "Notwithstanding criterion", insert "2.d.".

Delete "2.c.".

Page 22, II. Behavioral Health Care; A. Psychiatric Beds; Review Criteria; Criterion 10

After "of the psychiatric hospital's", insert "licensed tuberculosis".

After "beds", delete "of any licensure classification".

These changes revise Review Criterion 10 so that beds qualified for conversion are limited to those licensed as tuberculosis beds. Review criterion 10 will read as follows:

> Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application by a licensed psychiatric hospital for the conversion to psychiatric beds of the psychiatric hospital's licensed tuberculosis beds[~~of any licensure classification~~] shall be consistent with this Plan if the conversion does not increase the total licensed bed capacity of the psychiatric hospital.

Page 23, , II. Behavioral Health Care; A. Psychiatric Beds; Review Criteria for Psychiatric Services for Children and Adolescents; Criterion 4.b.

After "An inventory of", insert the following:

> all facilities with child or adolescent psychiatric beds in the ADD and the number of beds

Delete the following:

> current services in the ADD

Page 26, II. Behavioral Health Care; B. Psychiatric Residential Treatment Facility; Review Criteria; Level I PRTF; Criterion 9

After "9.", insert "An application".

Delete "Applications".

Page 27, II. Behavioral Health Care; B. Psychiatric Residential Treatment Facility; Review Criteria; Level II PRTF, Criterion 1 (and subsequent)

After "1.", delete the remainder of Criterion 1 and delete the notation "2.".

Renumber the subsequent review criteria 3. to 15. as 2. to 14., respectively.

The deletion includes:

> Approval of the application does not cause the total number of Level II PRTF beds to exceed 145 beds statewide;
>
> 2.

Page 29, II. Behavioral Health Care; B. Psychiatric Residential Treatment Facility; Review Criteria; Level II PRTF, Criteria 14, 15, and 16

In Criterion 14, which was renumbered as 13, after "of the State;", insert "and".
In Criterion 15, which was renumbered as 14, after "treatment"; delete "; and".
Delete all of Criterion 16, except the final period.
The deletion includes:

; and

16. Notwithstanding criterion 1, an application to establish PRTF Level II beds by a licensed Kentucky psychiatric hospital on the hospital's campus or through the use of existing space shall be consistent with this Plan

Page 30, III. Long-Term Care; A. Nursing Facility Beds; Definition
In the second paragraph, after "nursing home beds established", insert "as part of a".
Delete "under the".
After "(CCRC)", delete "provisions of this Plan".
Delete the definition for "Specialized Long Term Care." The deletion includes:

"Specialized Long Term Care" means a program of care provided in a licensed long term care bed for patients who require technically complex treatment with life supporting equipment or who have serious problems accessing appropriate skilled nursing care due to the specialized treatment required by their medical diagnosis and level of functional limitation.

Page 31, III. Long-Term Care; A. Nursing Facility Beds; Review Criteria; Criterion 4.d.
After "bed need;", insert "and".

Pages 31 and 32, III. Long-Term Care; A. Nursing Facility Beds; Review Criteria; Criteria 5 and 6
After "5.", insert the following:

Notwithstanding criteria 1, 2, 3, and 4, an application submitted by an existing facility that has met the emergency circumstances provision established in 900 KAR 6:080, Section 2, and has received notice from the Office of Inspector General, Division of Certificate of Need, that an emergency exists shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating an emergency specific to ventilator-dependent patients that require long-term ventilator services.

Delete the remainder of Criteria 5 and 6 in their entirety.
This deletion includes:

Notwithstanding criteria 1 and 2, an application to establish nursing facility beds in a Kentucky licensed acute care hospital shall be consistent with this Plan if the applicant demonstrates the following:

a. The overall utilization of nursing facility beds within the ADD is at least seventy (70) percent as computed from the most recently published inventory and utilization data;
a. The annual average length of stay for the proposed nursing facility beds shall not exceed forty-five (45) days;
b. At least fifty (50) percent of the patients admitted to the proposed nursing facility beds will have the primary diagnosis of:

i. Acute myocardial infarction (AMI);
ii. Heart failure (CHF);
iii. Pneumonia,
iv. Chronic obstructive pulmonary disease (COPD); or
v. Urinary Tract Infection/Septicemia;

c. Readmission rates for the acute care hospital applicant will decrease;

d. Seventy-five (75) percent or more of patients discharged from the proposed nursing facility beds will transition to a home or community based setting; and

f. The applicant agrees to submit an annual report on the average length of stay within their nursing facility beds, hospital readmission rates, and discharge disposition to the Cabinet for Health and Family Services; and

5. Notwithstanding criteria 1 and 2, an application submitted by a Kentucky licensed acute care hospital or Kentucky licensed nursing facility to add long term care beds restricted to a specialized long term care program shall be consistent with this Plan.

Page 33, III. Long-Term Care; B. Home Health Agency; Definitions

Revise the definition of "Home Health Agency" as follows:

- After "A 'Home Health Agency' is", insert "defined by KRS 216.935(2)".
- Delete the remainder of the current definition, except the period.
- Deleted language includes:

  a Medicare or Medicaid-certified agency licensed pursuant to 902 KAR 20:081 to provide intermittent skilled nursing services and other services for restoring, maintaining, and promoting health or rehabilitation to patients in their place of residence

Page 34, III. Long-Term Care; B. Home Health Agency; Review Criteria; Criterion 3

After "provision as", insert "established".

Delete "outlined".

Page 34, III. Long-Term Care; B. Home Health Agency; Review Criteria; Criterion 4

After "and contiguous counties", insert the following:

proposing to service exclusively patients discharged from its facility

With this insertion, Criterion 4 will read as follows:

Notwithstanding criteria 1 and 2, an application by a licensed Kentucky acute care hospital, critical access hospital, or nursing facility proposing to establish a home health service with a service area no larger than the county in which the facility is located and contiguous counties proposing to service exclusively patients discharged from its facility shall be consistent with this Plan if the facility documents, in the last twelve (12) months, the inability to obtain timely discharge for patients who reside in the county of the facility or a contiguous county and who require home health services at the time of discharge.

Page 35, III. Long-Term Care; C. Hospice Services; Need Assessment for Hospice Services

In the explanation of "Admissions" – after "*Report*", delete the period.

After the explanation of "Deaths", insert a paragraph break before the "Review Criteria" section.

Page 40, IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criteria; Criterion 4.

After "fixed site therapeutic cardiac", insert "catheterizations".

Delete "catheterization".

Page 40, IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criteria; Criterion 4.a.

After "an existing licensed", insert "Kentucky".

Criterion 4.a. will read as follows:

> The applicant shall be an existing licensed Kentucky acute care hospital;

Page 44, IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criteria; Criterion 7

In 7.a., after "a licensed Kentucky", insert "acute care (non-critical access)".

In 7.a., after "teaching facility of", insert the following:

> the University of Kentucky or the University of Louisville (collectively "Kentucky academic medical center") through a formal affiliation in the form of an agreement or a contract in place for at least two (2) years and specifically focusing on improving cardiology care in the service area or county of the applicant hospital

Delete "an academic medical center".

In 7.b., after "teaching facility of", insert "a Kentucky".

Delete "an".

In 7.c., after "teaching facility of", insert "a Kentucky".

Delete "an".

In 7.c., after "center;", delete "and".

In 7.d., after "service", insert the following:

> and has a population greater than 30,000

In 7.d., after "; and", insert the following:

> e. The applicant hospital has a minimum of 20,000 emergency department encounters on an annualized basis;

With these changes, Criterion 7. will read as follows:

> Notwithstanding criteria 1, 2, 3, 4, 5, and 6, an application to establish a comprehensive (diagnostic and therapeutic) cardiac catheterization service shall be consistent with this Plan if:
>
> > a. The applicant is a licensed Kentucky acute care (non-critical access) hospital affiliated with the cardiology program of the primary teaching facility of the University of Kentucky or the University of Louisville (collectively "Kentucky academic medical center") through

a formal affiliation in the form of an agreement or a contract in place for at least two (2) years and specifically focusing on improving cardiology care in the service area or county of the applicant hospital [~~an academic medical center~~];

b. The medical director and the cardiologists staffing the applicant's proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of a Kentucky[~~an~~] academic medical center;

c. The applicant hospital is located within fifty (50) highway miles of the primary teaching facility of a Kentucky[~~an~~] academic medical center;[~~and~~]

d. The applicant hospital is located in a county that does not have an existing cardiac catheterization service and has a population greater than 30,000; and

e. The applicant hospital has a minimum of 20,000 emergency department encounters on an annualized basis;

Page 44, IV. Diagnostic and Therapeutic Equipment and Procedures; A. Cardiac Catheterization Service; Review Criteria; Criterion 8

After "this Plan", insert the following:

; and

9. Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application to establish a fixed-site diagnostic cardiac catheterization service shall be consistent with this Plan if the following criteria are met:

a. The applicant is an acute care hospital that is providing diagnostic cardiac catheterization with intermittent equipment through a mobile license; and

b. The applicant is proposing to replace the mobile service at its hospital with a fixed-site, diagnostic cardiac catheterization service.

Page 45, IV. Diagnostic and Therapeutic Equipment and Procedures; B. Magnetic Resonance Imaging, and Page 46, IV. Diagnostic and Therapeutic Equipment and Procedures; C. Megavoltage Radiation Equipment

After the notation "B.", delete the section title, Definitions, and Review Criteria included for "Magnetic Resonance Imaging Equipment" in its entirety, and delete the notation "C.".

Page 47, IV. Diagnostic and Therapeutic Equipment and Procedures; D. Positron Emission Tomography Equipment

Before "D. Positron", insert "C.".

Delete "D.".

Page 47, IV. Diagnostic and Therapeutic Equipment and Procedures; C.[~~D.~~] Positron Emission Tomography Equipment; Review Criteria:

In 3., after "treatment services;", delete "and".

In 4., after "planning area"; insert the following:

; and

5. Notwithstanding criteria 1, 2, 3, and 4, an application submitted to establish or expand a mobile PET service shall be consistent with this Plan if the applicant provides documentation of an arrangement to provide services to a licensed acute care hospital or critical access hospital in the planning area and has the support of that hospital

Page 49, IV. Diagnostic and Therapeutic Equipment and Procedures; E. New Technology

Before "E. New Technology", insert "D.".

Delete "E.".

Under Review Criteria, Criterion 3.:

- After "equipment,", insert "an applicant".
- Delete "applicants".

Under Review Criteria, Criterion 4.:

- After "formulated,", insert "an applicant".
- Delete "applicants".

On Page 50, under Review Criteria, Criterion 5.:

- After "5.", insert "An applicant".
- Delete "Applicants".

Page 51, V. Miscellaneous Services; A. Ambulance Service; Definition

After "Definition", insert the following definition of "Ground ambulance services":

"Ground ambulance services" means services provided by a Class I, II, III, or IV ground ambulance transport agency. The license classifications are established in KRS 311A.030 and 202 KAR 7:545.

Delete the remaining language under the "Definition" heading in its entirety.

Page 51, V. Miscellaneous Services; A. Ambulance Service; Review Criteria; Criterion 1

Revise Criterion 1 as indicated here:

The applicant shall document that all agencies licensed to provide ambulance service or medical first response within the applicant's proposed geographic service area have[~~the appropriate local legislative body (fiscal court, city council, or both if applicable) has~~] been given notice of the applicant's intent to obtain a certificate of need. The notice shall describe the scope of service and proposed geographic service area with specificity[~~. For purposes of this requirement, the term "appropriate local legislative body" refers only to those legislative bodies that are currently licensed to provide ambulance services in the applicant's proposed service area~~]; and

Page 51, V. Miscellaneous Services; A. Ambulance Service; Review Criteria; Criterion 2

After "multiple providers propose", insert "advanced life support (".

After "ALS", insert a closing parenthesis.

Page 51, V. Miscellaneous Services; A. Ambulance Service; Review Criteria; Criteria 2 and 3:

After "meet the need", delete "; and" and all of Criterion 3., except the final period. The deleted language includes:

; and

3. Applications to provide only Class II or Class III services shall be accompanied by documentation (e.g., charts depicting response times of existing service, number of runs during the previous year, and comparable supportive data) that the need for scheduled or critical care inter-facility transportation is not being met by the existing emergency or other Class II or III ground ambulance services. In the presence of this evidence, priority shall be given to a competing application, if any, for the addition of vehicles, expansion of service areas, or comparable modifications that would allow an existing emergency ambulance service provider to meet any unmet need for critical care inter-facility or scheduled ambulance services

Page 52, V. Miscellaneous Services; B. Ambulatory Surgical Center; Definition

After "are performed", insert "<u>. An ASC shall</u>".

Delete ", and that".